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Patient-Focused Drug Development Public Meeting 10-27-2014

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FOOD AND DRUG ADMINISTRATION (FDA)
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

FEMALE SEXUAL DYSFUNCTION
PATIENT-FOCUSED DRUG DEVELOPMENT
PUBLIC MEETING

Monday, October 27, 2014

FDA White Oak Campus
10903 New Hampshire Avenue
Bldg. 31, The Great Room
Silver Spring, Maryland 20993

Reported by: Michael Farkas
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1 M E E T I N G R O S T E R

2 FDA PANEL

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4 Hylton Joffe

5 Audrey Gassman, M.D.

6 Christina Chang, M.D., M.P.H.

7 Marcea Whitaker

8 Theresa Mullin, Ph.D.

9 Ashley Slagle

10 Sandra Kweder, M.D.

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1 P R O C E E D I N G S

2 OPENING REMARKS

3 DR. EGGERS: One minute to still say
4 good morning and then it will be afternoon. We
5 are going to get started in a minute. So if you
6 want to take your seats. I see actually everyone
7 is all prepared for this. This is the quickest
8 we've ever gotten silent for one of these meetings
9 before. So I think we'll begin.

10 Good afternoon. My name is Sara Eggers
11 and I'm in CDER, the Center for Drug Evaluation
12 and Research in the Office of Strategic Programs.

13 I'd like to welcome you to today's
14 meeting on Female Sexual Dysfunction particularly
15 related to interest and arousal as part of our
16 agency's patient- focused drug development
17 initiative.

18 [Applause.]

19 Thank you. We -- give me one second. I can do
20 this on my own without any notes.

21 We have a very full day today and
22 tomorrow. And we have a lot of work to do on all

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1 of our parts. So I'm going to soon turn it over to
2 Dr. Audrey Gassman who will give a proper welcome.
3 But before we do I want to go over a few agenda
4 items and other details.

5 Oh, they we go. Okay. We're going to
6 start with FDA doing some talking first to set the
7 context by giving an overview of our patient-
8 focused drug development initiative, giving some
9 background on female sexual dysfunction and its
10 therapeutic options. And then I'll come back and
11 give an overview of the discussion format. I will
12 be serving as the facilitator today.

13 Our two primary topics are: number one
14 the disease symptoms and daily impacts that matter
15 most to patients. What is it about their condition
16 that bothers them the most; that bothers you the
17 most? And then topic two, what are your
18 perspectives on current approaches to treating
19 female sexual dysfunction particularly as it
20 relates to interest and arousal.

21 Those are our two main discussion topics
22 today. We will engage patients and patient

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1 representatives in the audience participating here
2 today and on the Web.

3 And then as we do for all of our
4 patient- focused drug development meetings, we
5 have a half hour for an open public comment at the
6 end of the meeting which will give anyone a chance
7 to make a comment even if it is not quite related
8 to the topics at hand. I believe the registration
9 for that has been -- we have filled to capacity
10 for that open public comment and Pujita will be
11 giving you more information then.

12 And then at the end we will wrap up and
13 do closing remarks for today. And then tomorrow
14 is our more scientific discussion on specific
15 issues related to drug development and evaluation
16 for FSD particularly interest and arousal.

17 There are a few housekeeping issues.
18 The restrooms are located about as far away as you
19 can go at the end of the hall that way. There is
20 a Kiosk that has basic food and we encourage you
21 to get up as you need. This is not a formal
22 meeting setting. So if you need to get up to use

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1 the restrooms, please do. Please silence your
2 phones.

3 We will be recording the transcript of
4 this meeting. We are also on the Webcast. So a
5 shout out to those of you on the Webcast, we
6 understand there is a very healthy participation
7 registration for the Webcast. It is great to see
8 so much interest in this meeting. So our Webcast
9 will be live right now and it will also be
10 archived on our Web site.

11 We also understand that there are media
12 outlets present. You probably noticed them on
13 your way in. And we are happy to see the level of
14 excitement and interest in this meeting. We just
15 want to make you aware that their presence is in
16 no way affiliated with FDA. And your
17 participation or your non-participation in any
18 kind of -- if they ask you to participate in an
19 interview, is completely at your discretion.
20 Okay.

21 With that I'm going to turn it to Audrey
22 who will give some welcome remarks.

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1 Thank you.

2 DR. GASSMAN: Thank you, Sara.

3 Good afternoon and welcome to today's
4 meeting on Female Sexual Dysfunction Patient-
5 Focused Drug Development. I'm Audrey Gassman,
6 Deputy Director of the Division of Bone,
7 Reproductive and Urologic Products, also known as
8 DBRUP in the Office of New Drugs at the FDA.

9 This is an important meeting and we are
10 looking forward to hearing from women who
11 experience sexual dysfunction and what they look
12 for in treatments for this condition. We're
13 pleased to see so many patients and advocates in
14 the audience. And I understand that there are
15 many others joining remotely from the Web. Thank
16 you again for being here and being part of this
17 meeting.

18 Today's meeting is one in a series of
19 what is called patient FDA's Patient-Focused Drug
20 Development meetings. Theresa Mullin will
21 describe this initiative in more detail in a few
22 minutes.

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1 Female sexual dysfunction is a complex
2 and multi-faceted disorder that affects women
3 across a wide spectrum of symptoms and severity.
4 Our meeting over the next two days will focus on
5 the most common form female sexual interest and
6 arousal disorder also known as FSIAD.

7 Later Christina Chang, our lead medical
8 team leader, will provide some brief background on
9 FSIAD.

10 I just want to say that we recognize
11 that this is a condition that can greatly impact
12 the quality of life.

13 The FDA is committed to supporting the
14 development of drug therapies for FSD. When we
15 discuss drug development over the next two days we
16 are referring to the process of identifying,
17 developing and evaluating potential therapies that
18 can help patients manage their FSD. FDA's mission
19 is to protect and promote public health by
20 evaluating the safety and efficacy of new drugs.

21 While we play a critical role in drug
22 development, we are just one part of the process.

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1 We do not develop drugs or conduct clinical
2 trials.

3 Drug companies often working with
4 researchers or patient communities are the ones
5 who will conduct the trials and submit
6 applications for new drugs to the FDA. We work
7 closely with the drug companies throughout the
8 drug development process. We are therefore glad
9 to see representation and tremendous interest in
10 today's meeting from industry, academia and other
11 government partners in the room and on the Web.

12 I want to spend a few minutes providing
13 a bit of background on the FDA's important role in
14 drug evaluation. For a drug to be approved for
15 marketing FDA must determine that it is safe and
16 effective for its intended use. Our regulatory
17 decisions are based on science, medicine as well
18 as legal and regulatory standards. First and
19 foremost the drug must demonstrate substantial
20 evidence of efficacy for its intended use. This
21 is a requirement by law.

22 Although the meaning of safe is not

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1 explicitly defined in the statutes or regulations,
2 the safety of a drug is assessed by determining
3 whether the benefits outweigh the risks. The FDA
4 makes each determination for a new drug based on
5 the totality of information provided by drug
6 companies in their new drug application which is a
7 request for marketing authorization in the U.S.

8 FDA's benefit risk assessment takes into
9 account many factors including the presence of
10 alternative therapies for the indication, the
11 goals of the proposed therapy, the magnitude of
12 the demonstrated benefit, and the nature of the
13 risks associated with the new product.

14 We take our roles very seriously. We
15 are aware of claims from external sources that the
16 FDA favors therapies in regard to men when it
17 comes to indications related to sexual dysfunction
18 or sexual difficulties. As a representative of
19 the Division and of the FDA I want to assure you
20 that we are willing and ready to work with all
21 sponsors and investigators to address these
22 conditions whether they are in men, women, or

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1 both.

2 We evaluate all applications
3 individually based on submitted evidence and do
4 not apply different standards or regulatory
5 standards when making our decisions.

6 Drug development for a female sexual
7 dysfunction is very complicated due to many
8 factors such as the ability to diagnose the
9 dysfunction, the presence of underlying medical
10 conditions that may be responsible for the
11 dysfunction, challenges identifying outcomes that
12 are both meaningful to patients and are
13 measurable, and challenges designing trials that
14 can reliably assess drug efficacy and safety.

15 FDA wants to help facilitate this
16 complicated process. For example, we advise all
17 sponsors who intend to treat symptom related
18 conditions including female sexual dysfunction to
19 consider our 2009 guidance on development of
20 patient- reported outcomes which provides
21 recommendations for development.

22 There are still many scientific issues

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1 that need to be resolved in this field. Tomorrow
2 we will have a discussion that will be more
3 technical in nature exploring important aspects of
4 drug development process for FSD. We will cover
5 topics that include diagnostic criteria, clinical
6 trial design and outcome measures.

7 Today's meeting, however, is about
8 listening to patients. We think very carefully
9 about the kinds of things we should be measuring
10 and evaluating for new drug for FSD and hearing
11 your perspectives on this will be invaluable.
12 Specifically we would like to hear from patients
13 what symptoms matter most and how they affect
14 daily life and sexual experiences. We are also
15 interested in understanding what patients are
16 currently doing to help themselves to treat this
17 condition.

18 What we hear from you today can help us
19 understand what patients would value in treatments
20 for FSD. Your input can help us understand how to
21 develop better end points to measure the aspects
22 of FSD that are important to patients and to

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1 develop better tools such as patient-reported
2 outcomes or PROs.

3 Sara Eggers will explain our meeting
4 format process which is designed to encourage a
5 rich discussion today.

6 I want to reiterate one point. The
7 important issues that I have mentioned are common
8 to the development and evaluation for any drug to
9 treat female sexual dysfunction. Therefore, our
10 goal today and tomorrow for that matter is to
11 explore these issues broadly and not focus
12 attention on any one specific drug or therapy.

13 Thank you again for your participation
14 and for being here today.

15 I'll now turn it over to Theresa Mullin
16 who will provide some background on FDA's overall
17 patient- focused drug development efforts.

18 DR. MULLIN: Hi. Theresa Mullin and I
19 direct the Office of Strategic Programs in the
20 Center for Drugs. And I just want to take a
21 minute to give you the background on this meeting
22 and it is one -- one way we look at this is one of

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1 a series of meetings that we are I'll say piloting
2 this approach to do a better job of more
3 systematically trying to collect information from
4 patients about their perspective on their
5 condition and the treatments available as Andrea
6 mentioned.

7 We understand that the patient's
8 perspective is quite critical to our understanding
9 and thus our ability to assess the benefits and
10 risks of any new therapy. Patients are the ones
11 who experience the disease; they are the ones who
12 will get any benefit that can be gotten from a new
13 drug; and also be the ones to experience the
14 risks. And so their role is quite critical and
15 unique in terms of informing our decision making.

16 And before this initiative began in 2012
17 we didn't really have a way to systematically
18 collect this kind of information. We had a
19 patient representative program that allowed us to
20 involve one or two patients in our process. And,
21 of course, because they would be involved in the
22 discussion of particular drugs we had to go

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1 through a lot of conflict of interest screening.

2 And we still have this program and it is very

3 valuable. But as you can hear it limits our

4 ability to get wider input. And we knew we really

5 needed to hear from as diverse and broad a

6 community as possible who is affected by any given

7 disease.

8 So we designed this program and included

9 it in our reauthorized prescription drug user fee

10 commitments that we made in 2012 and so we have

11 committed in that program to include at least 20

12 meetings in different disease areas over the five

13 years to sort of as I said pilot this approach and

14 figure out how we can optimize it to get the most

15 benefit both in the meeting and then in our follow

16 up to these meetings. This helps us better

17 understand and advise sponsors during the drug

18 development process and also, of course, also give

19 us more insight than we would have had in

20 reviewing any particular application that gets

21 submitted.

22 So -- just a minute, I need to find the

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1 advance key. Ah. Okay. Did I already -- did I
2 go twice? I'm sorry; my slides look so much alike
3 that - - oh there we go.

4 So this process just quickly started in
5 2012. We published a Federal Register Notice
6 which is our usual way of communicating to the
7 public with about 40 diseases in it. We asked for
8 comment. We got about 4,500 comments on that
9 list. And that helped us to sort of sort through.
10 We came up with a list of 16 that we are focusing
11 on in the first three years.

12 And then in this slide as you see there
13 is a Federal Register Notice there on October the
14 8th we published a list of diseases that we were
15 offering as candidates for the final two years of
16 the program, 2016 and '17 and we're hoping to
17 receive public comment by I think December the 5th
18 on what we will set up there.

19 And this slide shows you the diseases
20 that we are covering in those first three years.
21 The ones on the left for fiscal year '13 and '14
22 are ones we've already done at this point. And we

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1 are working our way through producing our reports
2 and following up on those.

3 And today's meeting is on female sexual
4 dysfunction. It is the first meeting we are
5 having in 2015 for this fiscal year.

6 And so as Andrea said each of our
7 meetings covers two essential areas which are:
8 What are the patients' experiences with the
9 disease? What are the most problematic aspects of
10 it? What are they doing to treat it today? What
11 are they -- there may not be any good treatments
12 available but what are they doing to try to cope
13 with the condition?

14 We start with those questions and we
15 tailor it further. The review division may have
16 other things they want to take advantage of having
17 you here today to hear about other things as well.
18 So for example we had a meeting on HIV Aids, we
19 took that opportunity to talk to the patients
20 about their perspective on cure research. Would
21 they be willing to forego the treatments that were
22 available to participate in a trial that involved

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1 cure therapy? And so there are things we can talk
2 to the patients or hear from them about that
3 provide a unique opportunity. We try to put those
4 into these meetings as well if we can.

5 And then we take what we learn here;
6 what we have found is the more active
7 participation, the more we get to hear from what
8 you think and the more patients who are able to
9 participate here in the room or on the Webcast or
10 through the Docket, the more we benefit and the
11 more of a rich source of information this gives
12 us.

13 So we are very happy, gratified to have
14 so many people here today.

15 And so the final slide I have here is
16 the report that we produce at the end of this
17 which is sort of our first deliverable, our first
18 product of these meetings is called the voice of
19 the patient. So following each of these meetings
20 we try to take the transcript and the other
21 information, our notes and write up the summary of
22 what we heard and try to capture it in the words

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1 that you used to tell us what you are experiencing
2 because those are really the most authentic way we
3 can record this and try to convey to the reviewers
4 today or beyond this what we heard and what you're
5 experiencing.

6 We take that report and use it as a way
7 to communicate in the future to our staff, to have
8 it as a reference document, and also to inform our
9 subsequent efforts that we may try to segue from
10 this into patient-reported outcome tools and other
11 ways to follow up longer term to give the full
12 benefit of this for future drug development in our
13 decision making.

14 And with that I'll turn it over to the
15 next speaker.

16 DR. CHANG: Thank you, Dr. Mullin. Good
17 afternoon everyone. Welcome to the Patient-
18 Focused Drug Development meeting on female sexual
19 interest/arousal disorder here at FDA.

20 My name is Christina Chang. I am a
21 clinical team leader in the Division of Bone,
22 Reproductive and Urologic Products here in CDER.

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1 And my division reviews the drugs that intended to
2 treat female sexual dysfunction or FSD for short.

3 My team is specifically responsible for
4 reviewing any clinical data that are submitted in
5 support of these applications.

6 We appreciate so many of you being here
7 participating in this workshop here on campus.

8 And also for those who are joining us via the Web.

9 And we are very grateful to those patients who are
10 willing to share the personal stories on a very,
11 very sensitive topic. So again very welcome.

12 And given the limited time that we have
13 and the complexity of the female sexual
14 dysfunction overall we would like to focus today's
15 workshop primarily on FSIAD or female sexual
16 interest arousal disorder.

17 The reason for today's meeting is that
18 although sexual dysfunction is not a life
19 threatening condition we do realize and recognize
20 that the dysfunction can significantly impact a
21 woman's quality of life. And its affects can
22 definitely result in major disturbances in family

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1 life. Service studies have suggested that women
2 more than men have complained about having sexual
3 difficulties and that these problems appear to be
4 very common in U.S. women. In this frequently
5 cited 1995 study women between the ages of 18 and
6 59 reported complaints to the investigators and
7 these complaints include lack of sexual desire,
8 difficulty in becoming aroused, inability to
9 achieve orgasm, anxiety about sexual performance,
10 reaching orgasm too rapidly, pain during sexual
11 intercourse, or failure to derive pleasure from
12 sex.

13 The 43 percent figure emerged from
14 analysis of responses from more the 1700 women.
15 Some critics have pointed out that the women in
16 the study were not specifically asked about
17 whether their complaints were severe enough to
18 bother them. And subsequently a lot of
19 discussions ensued on how we should define what
20 exactly constitutes female sexual dysfunction.

21 But it is not possible to talk about
22 dysfunction without first discussing normal sexual

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1 function. Normal sexual response in women depends
2 on a very complex web of interacting factors
3 including physiological, emotional, relationship
4 dynamics, and much, much more. Significant
5 changes in any of these components can affect a
6 woman's sexual desire, response and satisfaction.

7 Although the definition of sexual
8 dysfunction in women has been the subject of some
9 debate because it appears to be less quantifiable
10 what has not been disputed is that for a woman to
11 be diagnosed with a dysfunction her symptoms must
12 be severe enough to be a source of personal
13 distress. And as a 2008 study by Dr. Shifren (ph)
14 shows that an estimated 12 percent of U.S. adult
15 women may have sexual problems when their
16 diagnosis takes into account the presence of
17 personal distress.

18 So we went from 43 percent to 12 percent
19 but this is obviously still a significant segment
20 of the female population in this country.

21 I want to move on now to a brief
22 overview of the female sexual dysfunction as

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1 defined by the

2 American Psychiatric Association. FSD

3 is a term that covers a heterogeneous collection

4 of conditions and in the past FSD was classified

5 into four different conditions. The first:

6 Hypoactive sexual desire disorder characterized by

7 the absence or reduced interest in sexual activity

8 as well as not being receptive to a partner's

9 initiation of sexual activity. Second: Female

10 sexual arousal disorder characterized by the

11 inability to attain or maintain sexual excitement.

12 Third: Orgasmic disorder characterized by the

13 difficulty to attain orgasm despite sufficient

14 arousal. And the last being pain disorder where

15 women complain of pain during sexual intercourse.

16 In May of last year Hypoactive Sexual

17 Desire Disorder or HSDD and Female Sexual Arousal

18 Disorder or FSAD were combined into a single

19 diagnosis in the Fifth Edition of the Diagnostic

20 and Statistical Manual. The other disorders

21 remain relatively unchanged.

22 With FSIAD being a relatively new

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1 diagnosis we know that there has been limited
2 clinical experience and consequently we are hoping
3 very much to hear your thoughts on this new
4 diagnosis.

5 As outlined in the DSM5 here are the
6 features that are used to arrive at a diagnosis of
7 FSIAD. There are six symptoms that I have taken
8 verbatim from the diagnostic manual and as you can
9 see the first three as well as the fifth symptom
10 relate to the absent or reduced sexual desire.
11 The final three symptoms have to do with the
12 absent or reduced arousal.

13 The manual specifies that to qualify for
14 the diagnosis the patient must have had at least
15 three of these symptoms for at least six months in
16 duration. And specifically for two of the symptoms
17 namely number four and number six the manual also
18 mandates documenting the frequency when the
19 patient would notice these symptoms. So the
20 patients report these two symptoms, number four
21 and number six, occurring in at least 75 percent
22 of the sexual encounters.

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1 Furthermore the symptoms in the previous
2 slide must cause significant distress to the
3 patient.

4 However, what clinically significant
5 distress means exactly is not really defined in
6 the manual. And most importantly three other
7 contributors to sexual dysfunction must be ruled
8 out before making the diagnosis. First: the
9 problem with having either low desire or low
10 arousal cannot be explained by another psychiatric
11 disorder such as depression or anxiety.

12 Second: any relationship factors should
13 be considered before making a diagnosis. But here
14 again the manual does not elaborate on what these
15 relationship stressors may be or how severe they
16 have to be. It seems that there are many other
17 stressors besides partner violence such as kids,
18 work, other relationship dynamics, et cetera. So
19 we would like to hear your perspective. And
20 finally the third factor that needs to be
21 considered is: medical illnesses, medications or
22 any other substance use. So FSIAD is really

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1 almost a diagnosis of exclusion.

2 Additionally the manual outlines other
3 ways to describe FSIAD such as using a severity
4 grading, classified as mild, moderate, or severe.

5 Another way of categorizing the condition is
6 whether the patient has always had the condition
7 or it's something new in her sexual experience.

8 The third classification would be whether the
9 condition is situational such that it only happens
10 in specific environments with a particular partner
11 or whether the conditions is generalized meaning
12 that there are no identifiable triggers.

13 And as we all know there are no drugs
14 approved by FDA to specifically treat FSIAD, HSDD,
15 or FSAD. Some existing products have been studied
16 for these conditions. But these products have had
17 their own issues. For example Sildenafil or
18 Viagra was studied for the treatment of female
19 sexual arousal dysfunction or disorder but was not
20 shown to be effective.

21 Other products such as hormonal
22 therapies may have potential safety issues when

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1 they are taken long term.

2 Non drug therapies include behavioral
3 therapies or couples sex therapy. But we are not
4 aware of any large scale studies to support these
5 treatments.

6 So we are very interested in hearing
7 from the patients as to what remedies you've been
8 using to help with your sexual problems and
9 whether you feel that they've helped or not.

10 I also want to point out that for pain
11 associated with sex or the sexual pain disorder
12 FDA has actually approved several products. In
13 addition to several estrogen containing products,
14 we've recently approves Ospemifene for the
15 treatment of pain during intercourse that is
16 associated with vulvar or vaginal changes due to
17 menopause.

18 So part of the rationale for convening
19 this meeting today is our recognition that we do
20 not yet have drug therapies to help women with
21 either low sexual desire or low arousal.

22 And as I mentioned already when it comes

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1 to HSDD, FSAD, or FSIAD making the diagnosis
2 correctly is complicated. Accordingly developing
3 drugs to treat these conditions is also very
4 complicated. And this workshop presents an
5 opportunity that going forward the FDA industry
6 and the larger community could be hopefully on the
7 same page with respect to the terminologies
8 relating to these conditions. And identifying the
9 appropriate patients which really have dysfunction
10 in desire or arousal can help us move forward in
11 developing safe and effective drug therapies for
12 those who can really benefit.

13 From the discussion today we'd also like
14 to get a better sense from the patients on what
15 are the most important symptoms we should measure
16 in clinical trials to see if a drug can be a
17 benefit. And how shall we measure these changes.
18 These are very important parameters in assessing
19 whether a drug works for its intended purpose.

20 In order to help identify meaningful end
21 points for clinical trials the FDA is very
22 interested in patient-reported outcomes. Patient-

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1 reported outcomes or PROs can represent direct
2 measures of treatment benefit in identifying how a
3 patient feels or how a patient functions.

4 For conditions like FSIAD, HSDD, or FSAD
5 where a diagnosis is based on a more qualitative
6 than quantitative assessment input from the
7 patients is really essential. And we very much
8 would like to see well defined and reliable PRO
9 instruments developed, validated, and evaluated in
10 clinical trials for drug development.

11 I will just put in a plug for tomorrow's
12 program. We are also having a scientific workshop
13 tomorrow to discuss some of the very challenging
14 issues in developing drug therapies for these
15 conditions and we hope that many of you will be
16 able to join us tomorrow.

17 Thank you all again for being here. And
18 now let me turn it over to Dr. Sara Eggers.

19 DR. EGGERS: Thank you very much to all
20 of the FDA colleagues for providing that
21 background. We've got one more FDA speaker that
22 stands in the way of the discussion with you, so

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1 I'll try to make this as brief as possible.

2 This meeting today is quite different in
3 format and style from other public meetings you
4 may have attended. And as Audrey mentioned that
5 is really the goal; that is our intent is to have
6 a format that really encourages and enables
7 dialogue with patients.

8 The two topics that we are covering
9 we've mentioned this before but I'll go into a bit
10 more detail. One the symptoms that matter most to
11 you and in particular symptoms or aspects of your
12 condition that have the most significant impact on
13 your sexual experience, specifically and more
14 broadly on your daily life. And how specifically
15 do these symptoms affect your sexual experiences.
16 And how, if at all, do they change over time?

17 And then after the break we'll come back
18 and talk about the approaches to treating FSIAD.
19 What are you currently doing to treat your
20 condition and its symptoms? How well do they work
21 for you? What are their biggest downsides? And
22 importantly what would you look for in an ideal

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1 treatment? What specific things would you like --
2 aspects of your condition would you like to see
3 addressed?

4 As far as our format for each of those
5 two topics we're first going to ask a panel of
6 patients to share their stories with us and
7 provide a good foundation for a facilitated
8 discussion that will follow.

9 And those of you who are on Topic 1 if
10 you could please make your way to the front at
11 this time. Bring your name tags. If you don't
12 have tent card, I probably have it up here for
13 you.

14 These panel members were identified from
15 those when we put out the invitation in the
16 Federal Register Notice we invited people to
17 submit comments if they were interested in
18 presenting comments to start our discussion and we
19 identified women who experience a range of
20 symptoms, a reflective range of perspectives to
21 attend. So I thank you in advance for coming up
22 here.

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1 After they have their comments, there
2 may be some clarifying questions. But then we are
3 going to move out into the facilitated discussion,
4 really follow up and build on what we heard from
5 the panel discussants and ask more detailed
6 questions for that.

7 And the purpose here is to build on what
8 we heard from the panel and really get a sense of
9 what is more in depth and what range of
10 perspectives and experiences are out there.

11 So, we have staff floating around; you
12 don't have to get up to any microphones. We have
13 staff floating around who will bring the mic to
14 you. So when I ask a question, just raise your
15 hand and we're going to try to take everyone who
16 wants to speak. I have some ground rules that we
17 will go over in a minute.

18 We are going to ask that you please
19 state your first name. We don't need your last
20 name. Just your first name is fine before
21 speaking. And for the sake of transparency we
22 also request that at the time that you first speak

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1 and that includes the panel discussants as well
2 that you disclose if you are affiliated with an
3 organization that has an interest in FSD or if
4 your travel has been sponsored or if you have
5 significant financial interest in FSD drug
6 development. That is in the sake of transparency
7 and we'll just ask everyone to disclose that at
8 the first time that they speak.

9 And when we ask a question try to keep
10 your responses focused on the specific question or
11 topic at hand. You should have a chance to speak
12 on any topics as they come up. So that will
13 really help the conversation move forward. Please
14 try to keep those responses limited to a minute or
15 two.

16 I'm going to regularly ask through a
17 show of hands if you in the audience and the
18 Webcast can chime in as well, if you generally
19 share a particular view that was just experiences
20 so that we can really build on what one another is
21 saying.

22 So we also have a strong Web

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1 participation. And this is really important. We
2 want to hear from the women on the Web today as
3 well. Although we may not read or summarize all
4 of your comments today they are being reviewed,
5 they will be part of the public record and we are
6 incorporating them into our final reports.

7 We are also going to occasionally go to
8 the phones to give you on the Web another
9 opportunity to contribute as time permits. All of
10 you will have a chance to answer polling questions
11 and I am going to ask for the polling questions,
12 we will put them on the table please, there are
13 little clickers, okay so there are going to be
14 some clickers floating around and we are going to
15 ask that just women who identify themselves as
16 having FSD and particular interest in arousal to
17 take the clicker and to answer the questions.

18 This is not at all a scientific survey.
19 It is merely a discussion aid. It helps us
20 understand who is in the room and what
21 perspectives you might share and what your
22 experiences might be. So please don't treat this

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1 in any way as a scientific exercise.

2 But we do find that it really does
3 enable a discussion. We can build on things that
4 we hear from the polling.

5 We also importantly have a Public
6 Docket. We know that there are many, many issues
7 that you won't be able to talk about today and
8 many things that you wish you could talk about in
9 more detail and you all have the opportunity,
10 anyone in the audience, anyone participating in
11 the meeting whether you are a patient, patient
12 representative or not to contribute a comment,
13 follow up on what you have said at the meeting or
14 a comment that just provides your full story. And
15 if you have people who weren't able to attend the
16 meeting today we encourage them as well to share
17 their stories with us and your experiences.

18 On our Website you can see the
19 information for the Public Docket. A Docket is an
20 unfortunate word for a repository that you can --
21 it is a vehicle for us to get comments from the
22 public. So it is just a Website you are sending

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1 your comment to. When you go to Regulations.gov
2 if you follow our Web link you will get to a link
3 and just click on the comment now button.

4 There are other resources for you so the
5 FDA's office of Health and Constituent Affairs
6 really focuses on providing patients with
7 information that they need. And they are the ones
8 as Theresa mentioned run the patient
9 representative program. So if you have any
10 questions or you would like to follow up with
11 them, their information is here.

12 And also CDER now has a new Office of
13 Professional Affairs and Stakeholder Engagement.
14 And we have Ria Blakely (ph) is around; she is
15 right there in the back, has her hand raised.
16 Particularly if you are an organization or a
17 health care provider or others who wants to engage
18 with FDA you may feel free to reach out to Ria.

19 Our primary goal today is to enable a
20 fair and open discussion. To insure that I'd like
21 to go over a few participation ground rules. We
22 are here first and foremost to listen to women who

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1 experience female sexual dysfunction particularly
2 as it relates to interest and arousal. So we
3 encourage all participants with FSAID to
4 contribute to the dialogue. Your partners and
5 advocates are welcome, too, but we ask that you
6 focus your participation on helping further
7 understand women's experiences and perspectives
8 with respect to the questions posed. We are going
9 to try to accommodate everyone who wants to speak
10 and again if we don't get your full comments,
11 please go to the Docket.

12 For the advocate organizations and the
13 many, many health care providers that have
14 registered today we encourage you to listen to the
15 dialogue today and submit a comment to the Docket
16 that expresses your understanding as to the
17 dialogue which the input that we hear today
18 reflects your understanding of the women that you
19 work with, reflects their perspective and
20 experiences because we do want to make sure that
21 we do reflect the broad range of experiences that
22 are out there and perspectives that are out there.

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1 We are happy to see participants today
2 who represent research, industry and other
3 organizations. We do believe that this input is
4 important for you as well and we just ask you to
5 stay in listening mode today.

6 FDA staff is here to listen and to take
7 notes and to help ask follow up questions as the
8 day goes forward. We won't be able to address any
9 questions from the audience today that might
10 arise.

11 The purpose of tomorrow's meeting is to
12 discuss these issues, regulatory and drug
13 development issues in more depth. So if you have
14 a question and you are able to participate
15 tomorrow, I recommend that you hold it, see if it
16 gets answered there and there is Q&A sessions and
17 there are opportunities to ask those questions.
18 And if at the end of that time you still haven't
19 heard the answers that you are looking for, please
20 the contact information for Ria and for the Office
21 of Health and Constituent Affairs or there are
22 evaluation forms at the end of today's meeting

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1 that we are going to ask you to fill out, feel
2 free to write your questions and we will try to
3 address them in some way either directly or
4 indirectly.

5 As we described today our discussion is
6 focused on symptoms first and foremost and on
7 experiences with treatment and approaches. We
8 understand that there are other important issues,
9 many other important issues to insure that the
10 women with FSD get treatment and support that they
11 need. Our narrow focus today reflects FDA's need
12 for specific information as both Audrey and
13 Christina mentioned.

14 There are a few things that our
15 discussion will not focus on today. And that
16 includes specific issues with any particular
17 product or any particular drug under evaluation.

18 We are also not addressing the broader
19 question about whether there is or is not a need
20 for medical treatment for FSD. As Dr. Gassman
21 stated FDA is committing to supporting the
22 development of drug therapies for FSD. And our

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1 discussion may touch upon specific treatments and
2 this is appropriate. We do want to ask about
3 treatments. However, the discussion of those
4 treatments we hope is done in a way that helps us
5 understand those broader issues. What symptoms
6 are generally being addressed? How do you know
7 that that treatment is working? We don't really
8 necessarily care what treatment it is, what is
9 useful to us is to say well, how does a woman know
10 when a treatment is working? What specific things
11 it is addressing? And how meaningful is that to
12 you as patients?

13 The opinions expressed here today are
14 personal opinions. This discussion is going to
15 touch on very sensitive topics. I don't even need
16 to say that. We all know that this is a very,
17 very personal experience that all women are
18 facing, sexual experience. Everyone faces these
19 as very personal experiences. And we want the
20 women up here to feel comfortable talking about
21 their experiences and expressing their
22 perspectives. Therefore, demonstrating respect is

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1 of paramount importance. We expect everyone here
2 to be on that same page in terms of respect.

3 Please wait to be acknowledged before
4 speaking and then speak into the microphone. And
5 please do not direct your comment to or about any
6 specific individual and avoid negative language
7 and please keep side conversations to a minimum.

8 Okay. Got that over with.

9 Now let's move on. We want your
10 feedback to the meeting, we really do appreciate
11 the evaluations that we get and we do review them
12 carefully. We have another several meetings
13 moving forward and what we learn from each of
14 these meetings really helps us with the next.

15 Does everyone have a clicker who wants a
16 clicker? We have a few of the polling questions
17 and these just again give us a sense of who is in
18 the room and who is on the Web at this point. So
19 we start with an easy one. This will help you
20 practice with the clickers as well.

21 So where do you live, where are you
22 coming from; a) if you are inside the Washington,

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1 D.C. metro area and b) if you are from outside?

2 As we expected this is an issue that has
3 a very wide geographic representation here today
4 so we thank you. We thank you all whether you
5 traversed the beltway everyday and so this is
6 something you routinely do or if this is one of
7 the rare occasions when you have to do so.

8 Are you participating today because you
9 personally are significantly bothered by: a)
10 absent or reduced desire for interest in sexual
11 activity or sexual fantasies; b) absent or reduced
12 sexual excitement, sexual pleasure or sexual
13 arousal during sexual activity; c) both; d)
14 neither but you have some other symptom associated
15 with FSD? And if none of these apply, just don't
16 answer the question.

17 We'll give some time.

18 Okay. So a lot of you here are battling
19 with both of these. We will delve into these, try
20 to tease them apart a bit and for those of you
21 that feel that only one or the other, we will try
22 to get your experiences on how you experience the

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1 one but not the other and how those experiences
2 are for you.

3 What is your age?

4 We have a range of ages represented
5 here. It is really wonderful to see so many people
6 who are younger than 30 here participating today
7 as well as the entire range. This differing of
8 the age range indicates that you might have
9 experiences that are very different depending on
10 whether you have or have not gone through
11 menopause.

12 Can I back up a minute? I neglected to
13 ask about the Web polling results for the previous
14 question about what their interest is in this
15 meeting.

16 MS. GIAMBONE: Yes, we have about 55
17 percent of the people on line voted for absent or
18 reduced desire or interest in sexual activity or
19 sexual fantasies. And for question 3 we have for
20 the age we have about one third of the people
21 between the ages of 31 to 40 and about 30 percent
22 of the people between 51 and 60.

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1 DR. EGGERS: Okay. Thank you.

2 Have you received a diagnosis of Female
3 Sexual Interest or Arousal Disorder, FSIAD,
4 Hypoactive Sexual Desire Disorder, HSDD, or Female
5 Sexual Arousal Disorder, FSAD from a health care
6 provider?

7 Okay. So it looks like we have a mix of
8 both.

9 From here on I get tongue-tied very
10 easily so I am going to just say FSD from now on
11 and by that we mean FSD with particular focus on
12 interest and arousal. But if I have to say either
13 the acronyms out we could be here until tomorrow.

14 How long have you had symptoms of FSD?
15 Less than five years, five to ten, ten to 20, more
16 than 20, or you are not sure.

17 Okay. This is also a very nice mix of
18 experiences that we have here. We are going to
19 try to tease apart some of that a little bit as we
20 go on.

21 And on the Web?

22 MS. GIAMBONE: 50 percent of the people

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1 on the Web said that they have had symptoms from
2 five to ten years.

3 DR. EGGERS: Okay. That is it for our
4 polling questions for now. And we have a few more
5 as the two discussion topics unfold. But thank
6 you very much for answering those.

7 And now it is time to move into the
8 Topic 1 discussion. And again this is on -- and
9 everyone you have the agenda and the questions
10 that we posed in our Federal Register Notice that
11 were the focus of today's discussion are printed
12 on the last page or the back of that agenda. This
13 is very much just a summary of those to fit on one
14 slide. But we've gone over what the main point of
15 this discussion is.

16 A few other things we want to know is
17 about if your symptoms wax and wane over time. We
18 have a few questions about if you are asked to
19 rate your symptoms. We have some considerations
20 we'd like to get from you. And then finally we'll
21 talk about what worries you about that distress
22 portion as we get into the facilitated discussion.

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1 But to kick it off we are going to have
2 each of the four of you go. I know you all by
3 phone, by name, but I don't -- they should have
4 printed your names on the other sides of the

5 VICTORIA: Do you want me to start?

6 DR. EGGERS: You can start. Oh and when
7 you -- just push it once.

8 VICTORIA: Hello. Okay. My name is
9 Viki and I have to say at first Veritas has taking
10 care of my travel expenses through grants from
11 Sprout Pharmaceuticals, Even the Score, and the
12 Institute for Sexual Medicine.

13 So starting off I'm 39 years old. I'm
14 here to tell my story about my experience living
15 with HSDD. My symptoms became significantly
16 noticeable about five years ago after the birth of
17 my fourth child. A couple years before that I had
18 experienced a slight decrease in desire and fewer
19 sexual occurrences but I figure it was just
20 because we were both busier in our lives.

21 I realized that there was something more
22 going on with me when I started to just not want

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1 to have sex at all. I stopped initiating sex and
2 my desire became nonexistent. This was not normal
3 for me. My husband and I had a very fulfilling
4 and healthy sex life up until this point. Our
5 friends would even make comments about how we
6 couldn't keep our hands off each other.

7 I sought out answers from different
8 specialists to find out what was happening to me
9 and if there was something I could do. I had an
10 array of tests done spanning from full panel blood
11 work to hormone testing to even internal
12 ultrasounds. No one had any answers for me when
13 all of my tests came back normal. But I knew
14 there had to be something else going on.

15 My mom told me I should go to San Diego
16 to see Dr. Goldstein because she was a patient of
17 his and he may have answers for me. I was
18 reluctant at first because I had already spent so
19 much money on testing and my insurance would not
20 cover any test that had to do with hormones. My
21 mom felt it was so important for me to see him
22 that she flew me to San Diego and he diagnosed me

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1 with HSDD.

2 My symptoms rapidly worsened over the
3 last three years. I found myself avoiding any
4 situations where a sexual experience may occur.
5 For example going to bed after my husband fell
6 asleep or jumping out of bed in the morning before
7 -- sorry, before he got up just so he wouldn't try
8 to initiate sex. I even found myself avoiding
9 simple hugs and kisses.

10 The defining moment for me was when my
11 husband and I took a vacation for a week to Mexico
12 without kids. This was supposed to be a time for
13 the two of us to relax and enjoy each other. In
14 the past when we had taken vacations together we
15 barely left the room. My mom always joked "don't
16 get pregnant" when we left. But unfortunately my
17 symptoms stayed the same. In a beautiful place
18 with the man I love my body was like a shell with
19 nothing inside. I just did not feel like I wanted
20 to have sex. My desire was still gone. This was
21 devastating to both of us and definitely put a
22 strain on the trip.

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1 My sexual experiences recently are more
2 out of obligation to keep my husband satisfied
3 after all it is not his fault this is happening to
4 me.

5 I feel it is important to say my husband
6 and I talk very openly about HSDD. I know he
7 loves me very much and tries hard to understand.
8 He does not have any problems as far as his sexual
9 function or desire. So it is difficult for him to
10 relate.

11 I would like to note if he did have a
12 problem with sexual dysfunction as a man he would
13 have many options for treatment. But that being
14 said it has put a big strain on our relationship
15 and he has said to me that he feels stupid at
16 times and he keeps getting shut down. I know he
17 feels rejected.

18 This is the last thing I want the man I
19 love to feel. It makes me feel so guilty and
20 frustrated. I can't be the woman he married.

21 So I think to myself I'm only 39 years
22 old am I just going to be like this forever. What

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1 does it mean for my future and the future of my
2 marriage? Is there no hope for me to get back the
3 feelings I had before? Women like me who feel
4 this way need a solution. We deserve to feel our
5 sexual desire again.

6 Thank you.

7 DR. EGGERS: Thank you very much
8 Victoria.

9 BEVERLY: Good afternoon. My name is
10 Beverly. And Veritas arranged my travel here
11 today. But I do have to tell you I would be here
12 regardless; I'm quite passionate about the subject
13 so I appreciate the opportunity that the FDA has
14 given me to come here today and talk to you and
15 tell you my story.

16 I'm hoping that hearing my personal
17 story about how I've suffered with this medical
18 condition will help you understand why women need
19 help. I started out having this issue about four
20 years ago. Initially I thought it was just going
21 to be something that passed quickly.

22 It started because I had an allergic

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1 reaction to a medication. Then my whole life
2 changed. It basically turned upside down.

3 I saw over 30 doctors in a variety of
4 specialties before I found treatment. I am about
5 \$35,000 into this issue at this point. I started
6 with my personal gynecologist, moved on to my
7 general practitioner, my concierge doctor, saw
8 specialists at major teaching and research
9 hospitals, sought out the help of top
10 urogynecologists, endocrinologists and other
11 specialties. I wasn't getting any help. But I
12 wasn't going to stop.

13 I endured pudendal nerve injections
14 because they might work. I was given anti-
15 depressants which ironically make it even more
16 impossible for you to orgasm. Anybody who didn't
17 know that? Muscle relaxers, pain killers, I've a
18 drawer full. Then I had life threatening things
19 like face swelling, rapid heartbeat, major weight
20 loss. No one could find the root of my problem.
21 But I kept getting prescriptions for things that
22 didn't help.

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1 In case you are unfamiliar with the
2 condition I'll share some of the things that I
3 experienced as symptoms. They include, not
4 limited to, but pain, depression, inability to
5 maintain relationships, loss of interest, loss of
6 ability to get aroused, low self-confidence,
7 inability to achieve orgasm, inability to maintain
8 relationships with your friends, your family. It
9 really impacts your self esteem and you have to be
10 an advocate for yourself because there is really
11 no help out there.

12 I run a small business. I'm an
13 entrepreneur. I have to get up every day and go
14 out and interact with people at high levels in the
15 community. I almost lost the ability to do that.

16 I adopted a daughter from Russia when
17 she was nine years old. When this hit she was
18 about 15 years old and needed me most. I lost at
19 least three years with her. And I'll never regain
20 that time.

21 I think the thing that makes me most
22 angry and most disappointed is that if I went to

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1 my doctor and I was a man and I said these things
2 they would be able to write me a prescription
3 within a couple of minutes for a drug that is
4 insurance covered and FDA approved. I don't know
5 how all their drugs got through approval but I'd
6 like to know who is behind that.

7 I probably spent 50 hours in manual
8 pelvic floor physical therapy thinking that might
9 be the problem. And yes that is just as personal
10 and intrusive as it sounds.

11 Fortunately for me I didn't believe all
12 those other doctors and I didn't take all of those
13 other drugs for any period of time particularly
14 when they had life affecting threatening side
15 affects like face swelling.

16 I found Dr. Goldstein and I received
17 some treatment from him. He had the answers, he
18 did different blood panels. He did some other
19 testing. I even talked to a sex therapist in his
20 practice who confirmed this was not in my head but
21 a physiological issue and medical condition.

22 Prior to the onset of this I had a very

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1 robust and fulfilling sex life.

2 Now that I'm being treated I don't have
3 issues with arousal, interest, or orgasm. All of
4 those things are possible. I have a great and
5 supportive significant other. Unfortunately I
6 lost a major relationship to this issue. And I
7 never want to go back there.

8 The topic is never far from my mind.
9 I'll never forget how it impacts my life. And I
10 know it could come back at any time.

11 My significant other is very aware of
12 how my symptoms wax and wane. He knows when my
13 treatment is due. It is very evidence in how I
14 initiate or how interested I am or how aroused I
15 get. I can tell you for sure there is a direct
16 correlation.

17 Recently I appealed to my insurance
18 company who declined to pay for any of my
19 treatments. We went to full third party medical
20 appeal. Unfortunately they determined it was not
21 medically necessary and told me that no future
22 appeal will be possible. The biggest thing that

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1 scares me is someday I might not be able to afford
2 the treatments I get. And if I were a man every
3 treatment I've gotten would be covered.

4 In closing I would just like to express
5 that I was passionate about this and honestly
6 quite angry about it as I started to prepare to
7 come here to tell my story. After I was briefed
8 by Sara from the FDA about my participation I
9 honestly was dismayed and it became fairly
10 profound. She was delightful to speak with when
11 she told me about what to expect here today.
12 Unfortunately when she told me not to set my
13 expectations too high as nothing was likely to
14 happen quickly you can understand that I was very
15 surprised and more than disappointed.

16 I feel strongly that we need this to
17 happen quickly. We need approval. We need
18 doctors to get educated. We need people to
19 understand this is a severe medical condition.
20 And we need women to stop suffering in silence.

21 I know none of you want your mothers or
22 sisters or daughters to go through this. It is an

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1 unmet medical need. And no amount of talk therapy
2 is going to fix it. We can't get better from a
3 physiological need by talking about it. I would
4 just be delighted if we had the same choices as
5 men.

6 Thank you for the opportunity to tell my
7 story.

8 DR. EGGERS: Thank you, Beverly.

9 And then Carol. Beverly if you could
10 shut off your microphone.

11 CAROL: Good afternoon. I welcome the
12 opportunity to participate in this meeting and
13 tell my story. By sharing this experience I hope
14 that it will assist and support women who are
15 currently sexually dysfunctional as well as those
16 who will experience it in the future.

17 I devoted a significant amount of time
18 and energy on my quest for an answer, a solution,
19 a treatment. I consulted numerous physicians and
20 specialists and experimented with various pills,
21 injections and topical medications.

22 My symptoms waxed and waned based on the

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1 type of medication, its delivery system, dosage
2 and the period of time I was on it. I experienced
3 brief honeymoon periods when I was sexually
4 functioning 75 to 80 percent. However, once the
5 affect of the drug began to wear off I was back to
6 where I started.

7 In my case there was an active interplay
8 between my physical symptoms and the psychological
9 aspects of my condition. For clarity sake I would
10 like to discuss these separately.

11 A first and most frustrating symptom was
12 the loss of my skin sensitivity. The skin
13 numbness felt like my entire body was encased in a
14 rubber glove sealing off all physical sensation.
15 Another analogy would be having my body injected
16 with a physical numbing agent like Lidocaine or
17 Novocain. The second and related symptom was that
18 I could not have an orgasm. I could not become
19 lubricated, aroused or sexually excited even after
20 sexual stimulation. No matter how intensely I
21 tried I attempted to talk myself into climaxing, I
22 never succeeded. I never succeeded and had no

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1 history with this type of condition and never
2 experienced sexual dissatisfaction in the past. I
3 became so frustrated that any attempt to have
4 sexual intercourse would end up in me crying.

5 The onset of both of these symptoms
6 began when I was in my early 50s. It was a very
7 gradual process over a period of months and became
8 progressively more pronounced. It began with
9 small subtle physical changes. The ability to be
10 stimulated by being touched slowly disappeared.
11 Sexual arousal and response time kept taking
12 longer and longer until it became nonexistent.

13 I had difficulty coping with my new
14 reality. Come to terms with the discrepancy
15 between who I was and who I became. I felt
16 sexually unattractive, inadequate, dysfunctional,
17 isolated and asexual. My primary concern was that
18 I would never be able to experience sexual
19 pleasure again.

20 After several years, a significant
21 amount of determination, patience, trial and
22 error, and the support of an excellent physician

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1 and the correct dosage of medication my condition
2 finally stabilized. I'm able to climax, however,
3 my skin sensitivity has never been completely
4 restored.

5 Part of getting older is learning to
6 accept the things you cannot change, the courage
7 to change the things you can and the wisdom to
8 know the difference.

9 Thank you.

10 DR. EGGERS: Thank you very much Carol.

11 And finally we have Karen.

12 KAREN: In 1971 at the age of 23 I had
13 to make a careful decision about the type of birth
14 control I would use after the birth of my first
15 and only child. My mother-in-law had had a stroke
16 at age 45 and was paralyzed for the rest of her
17 life. She was in the first wave to use the then
18 revolutionary birth control pill of the 1960s. My
19 doctor recommended the brand new Dalkon shield IUD
20 which was being marketed as the Cadillac of
21 contraception. The advertising brochure I
22 received boasted that it was 100 percent safe with

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1 no general effects on the body.

2 12 years later at the age of 35 my
3 reproductive sexual life and sexual life were
4 forever altered when I had to have a total
5 hysterectomy including the removal of my ovaries.
6 During my recovery I learned that the Dalkon
7 shield caused the cumulative damage from the
8 pelvic inflammatory disease that went undiagnosed
9 and untreated for 12 years.

10 The Dalkon shield debacle went down into
11 history for being the most egregious breach of
12 medical misconduct. The doctor inventor made a
13 number of ethical lapses in the reporting of his
14 research results. Tens of thousands of women
15 suffered a wide range of pelvic damages.

16 I was please when I came through the
17 building today to see a display case out front
18 with former defective products and for all you to
19 see the Dalkon Shield IUD, it's out there. At the
20 time the FDA did not approve devices and it was
21 precisely because of this case that the FDA began
22 to approve devices as well as drugs.

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1 My hysterectomy left me traumatized in
2 shock, psychically devastated by the loss of my
3 fertility and my precious highly erotic
4 relationship with my husband. My bodily and
5 psychic symptoms were severe for many years. I
6 had a total loss of sexual desire and arousal.
7 Orgasm was out of the question.

8 As I now know the loss of the sexual
9 pelvic organs has a profound effect on sexual
10 function. In the 1980s, however, doctors were
11 still claiming that the only loss from a
12 hysterectomy would be the ability to get pregnant.

13 My eventual recovery included retooling
14 my career as a teacher to become a sexuality
15 educator. I hope to educate other women about the
16 sanctity of their sexual organs and how they could
17 make more informed decisions than I did as a young
18 woman.

19 Over time I was able to regenerate my
20 sexual interest and capacity although I never
21 fully recovered. At best I have been able over
22 time to have what I call a feeble orgasm. I

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1 incorporated what I had learned about positive
2 sexuality and sensuality techniques to enhance my
3 sexual experiences. However, there has always
4 been an ebb and flow.

5 Life stressors presented challenges to
6 my capacities. For me the loss of a good job, the
7 illnesses and deaths of my parents, et cetera
8 added to that ebb and flow in my sex life. Those
9 stresses and the PTSD of the hysterectomy make my
10 symptoms sometimes better and sometimes worse. At
11 present I am dealing with the death of my dear
12 husband. This loss has cause another major
13 stressor to my sexuality a natural consequence of
14 losing the love of my life.

15 The challenge of aging also presents an
16 additional issue to my sexual functioning at this
17 time. At the ripe old age of 67 I turned to my
18 sexuality profession and became the cofounder of
19 what is now the Sexuality and Aging Consortium.

20 Here is a warning, the boomers are
21 coming.

22 [Laughter.]

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1 Literally and figuratively and they, we, will
2 demand sexual access in those long term care
3 facilities that we may enter in a few years. Our
4 society and health care community at large are ill
5 equipped to deal with this phenomenon. So much
6 ignorance pervades our stereotypes of old age.

7 For my part I accept the reality of my
8 age and past challenges. I do not hold an
9 unrealistic expectation associated with the
10 cultural pressures to be forever young, beautiful
11 and sexy. I, and many other women, young or old
12 are not ever going to achieve the mind blowing
13 nirvana of orgasmic ecstasy that saturates our
14 popular culture. I am confident that one day I
15 will return to a satisfying form of sexual
16 expression whether it be self-love, wink wink,
17 and/or partnered coupling. I don't think of
18 myself as a cougar. I am more of a kitten. You
19 won't hear me roar but if you listen carefully you
20 might hear me purr.

21 Thank you.

22 DR. EGGERS: Thank you very much Karen.

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1 I would like to extend a round of
2 applause to all of the women up here.

3 [Applause.]

4 We know this is very personal to talk about and we
5 very much appreciate that.

6 Unless my colleagues have any clarifying
7 questions for any of the panelists, I'm going to
8 grab a microphone and make my way to the front.

9 DR. KWEDER: Sara I do have a question.

10 DR. EGGERS: Yes, go ahead.

11 DR. KWEDER: Two of the panelists I
12 think it was -- let's see it was Beverly and Carol
13 both said they are currently being treated. I
14 thought that is what you said. And so if you
15 could say what the treatment is, if it is
16 medication or some other form of therapy that
17 would be helpful.

18 BEVERLY: Sure I am happy to share that.
19 I am currently being treated with implanted
20 testosterone pellets.

21 CAROL: I'm also taking testosterone but
22 I am using a localized gel every day.

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1 DR. EGGERS: And we will be addressing
2 those products a little bit more in Topic 2.

3 Any other -- Marcea, please?

4 MS. WHITTAKER: Yes. I have a question
5 for Beverly. Thank you again for your story. You
6 mentioned that your partner knows when you need
7 treatment. Can you expound on that a little bit?

8 BEVERLY: Certainly. I am more than
9 happy to expound on it. The issue with arousal
10 and interest is really what is at question here.
11 And we have a very robust sexual life. But when
12 I'm not interested or I'm not initiating or I'm
13 not interested in his advances it becomes very
14 clear that the pellet that is inserted in me is
15 wearing off. Because we don't have any other
16 stressors in our relationship, there are no issues
17 in our life. And so the only thing that really
18 comes into play is that treatment needs to happen
19 again.

20 DR. EGGERS: Okay. So I'm going to
21 start off by asking for a show of hands how many
22 of you heard your own experiences reflected in at

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1 least one of the panel member's comments today so
2 far?

3 Great. Thank you.

4 Anyone who said my experience is nothing
5 like what any of the women are talking about up
6 here?

7 Okay.

8 At the end if we haven't addressed your
9 different situations we'll come back to you. But
10 I think that is reassuring that the range of
11 experiences, we did hear a range of experiences
12 presented this afternoon and we are now going to
13 build upon that in a little bit.

14 We do have a polling question. Before
15 we get to that I want to ask a few questions on
16 terminology. And I'm -- many of you said that you
17 experienced both in one of the first polling
18 questions that you had, both difficulties with
19 interest and difficulties with arousal. And if
20 someone would like to share what's the difference
21 between those two, how do you conceptualize those
22 differently? If you are interested in sharing

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1 just raise your hand and we'll come to you with
2 the microphone; if you could just state your name;
3 and if you have any of those disclosures to make.

4 MS. GOLDSTEIN: Hi, I'm Sue Goldstein.
5 I paid for my own travel and what else am I
6 suppose to disclose?

7 DR. EGGERS: If you are affiliated with
8 any organizations that have an interest.

9 MS. GOLDSTEIN: Okay. I am here as a
10 patient. But I'm also here as a sexuality
11 educator and author and I've interviewed a lot of
12 patients. I'm a clinical researcher so I have
13 talked to a lot of patients and I'm also on the
14 Board of the International Society for the Study
15 of Women's Sexual Health.

16 I think as a patient differentiating
17 between desire and arousal if you are interested
18 in having sex or if you are receptive to your
19 partner approaching you that is desire. When you
20 are getting wet, when you are getting tingly, when
21 you are having those bodily changes in bed or as
22 you are approaching the bed I think that -- it is

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1 the wetness that is the arousal. So while you
2 have the interest and your body may be starting to
3 get turned on, that is desire. But once you start
4 getting your body actually changing, it is the
5 getting wet, it is the -- maybe it is your nipples
6 getting erect, your clitoris getting engorged,
7 enlarged. Those bodily changes are the arousal.
8 So I think that one of the biggest problems is you
9 may not have an arousal issue but if you have no
10 desire your body isn't going to be aroused until
11 perhaps your partner starts stimulating you and
12 then you have bodily arousal and then maybe you
13 may have more interest. But the arousal can't
14 just occur standing there looking at your hot
15 husband or maybe you don't have a hot husband. I
16 am married 40 years and I still think my husband
17 is hot. But they are two separate things. But
18 there is -- certainly there is an interplay but
19 that doesn't mean that they are the same thing.

20 MS. EGGERS: We will be exploring that I
21 think throughout our conversation.

22 How many of you did that -- did Sue's

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1 comment resonate with that is how you
2 conceptualize it as well?

3 Okay.

4 Any completely different
5 conceptualizations?

6 Do you want to -- right here.

7 LEONORE: I think that it is enormously
8 diverse. I don't think that you know all the
9 words sounded good but I think if we sat down had
10 a more personal conversation differences would
11 emerge.

12 DR. EGGERS: And I think we should take
13 this point to heart for all of the -- what was
14 your name?

15 LEONORE: Leonore. We should take
16 Leonore's point to heart for all of our discussion
17 about just how variable and personal these will be
18 to everyone.

19 So a show of hands if you could, there
20 were a couple of panelists or maybe all of you who
21 indicated that you used to have one kind of normal
22 regarding your sexual experiences and now you face

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1 a distinctly different normal, your experiences
2 have changed. How many of you and if you feel
3 comfortable raising your hand experienced that
4 same thing where you had a one type of sexual
5 experience and normal about that and now it is
6 completely different.

7 Okay.

8 Are there any show of hands where this
9 has been your normal for as long as you can
10 remember that for your sort of adult life you've
11 always been living with this normal?

12 Okay.

13 So most of you this has sort of had an
14 onset; but we do have a couple of you who have
15 been dealing with this most of your lives. That
16 is helpful to set the context.

17 I'd like to go to a polling question
18 now. And these are just again to start a
19 discussion.

20 We'd like to know for those of you who
21 experience absence or reduced sexual interest
22 which of the following affects do you consider to

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1 have the most significant impact on your daily
2 life. And you can choose two. It is just a
3 discussion starter including other if there is
4 something other. So a) no or reduced interest in
5 sexual activity, b) no or reduced sexual or erotic
6 thought or fantasies, c) no or reduced initiation
7 of sexual activity, d) not being responsive to my
8 partner's attempt to initiate sexual activity. Or
9 again other. Pick two that are the most important
10 to you.

11 And on the Web we encourage you to
12 answer the same question.

13 Okay. Well you've made my job
14 difficult. We are going to be exploring a lot of
15 these issues. So about equal numbers of a), c),
16 and d) with less for erotic or sexual thoughts or
17 fantasies.

18 So let's explore a few of these in a
19 little bit more detail. And I'm going to start
20 with the response to you partners initiation which
21 is d) here. Any of you, you didn't just have to
22 pick the polling choice for this. Any of you can

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1 please comment on this. Are your sexual
2 activities, this is maybe an easy question. Are
3 your sexual activities typically initiated by you,
4 your partner or both? You? Your partner? Both?
5 Okay.

6 So it appears that the role of your
7 partner's initiation is very important to your
8 sexual experience.

9 How do you conceptualize when we talked
10 about responsiveness to that initiation? When you
11 saw this question what were you -- what was going
12 through your minds when you said about being
13 responsive? What happens? Can anyone describe
14 anything that happens to you physically or
15 mentally when your partner is initiating?

16 MS. PRICE: I'm Carla Price. The
17 biggest thing that I feel is anxiety because I
18 know that I'm not going to be able to respond
19 back. So I just tense up, I'm anxious. And like
20 one of the speakers said I definitely try to avoid
21 it at all costs. So I'll stay up late. I get up
22 early. Avoid any alone time. And my children are

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1 married and out of the house so I don't have a lot
2 of stresses other than this and it really shows.

3 DR. EGGERS: Thank you Carla.

4 Would anyone else like to comment? We
5 had one over here. Anyone else? There in the
6 back.

7 UNIDENTIFIED PERSON: I'll say hey, let
8 me just finish doing the dishes or close my
9 computer and make some space for this.

10 DR. EGGERS: And what is going through
11 your head, if I can ask?

12 UNIDENTIFIED PERSON: Well, it hadn't
13 occurred to me but it occurs to him so okay I'm
14 open for that.

15 DR. EGGERS: Okay. Would anyone else
16 like to share any kind of physical or mental
17 responses? Yes, Beverly?

18 BEVERLY: It is interesting because what
19 goes through my head is am I going to be able to
20 orgasm during this and is that going to impact how
21 he feels about our relationship because honestly
22 that is a huge part of men's self worth if they

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1 can get you there. And I've seen the wheels
2 almost come off my relationship a number of times
3 when that piece is lacking. So if I know my
4 treatment is wearing off I tend to avoid sex
5 because I know that that is going to create an
6 issue.

7 DR. EGGERS: Thank you.

8 Let's talk about your own initiation.
9 If it happens that you initiate sex, does your
10 experience differ at those times than if your
11 partner has initiated sexual experience
12 physically, mentally or emotionally? Is it a
13 different experience? Is it the same experience?
14 Show of hands. Is it the same experience?

15 Okay. Go ahead.

16 BEVERLY: I would say it is a vastly
17 different experience. If you are feeling aroused
18 and you are feeling interested and you want to
19 initiate sex the likelihood that you are going to
20 have a successful exchange in bed or wherever you
21 decide to have sex is much higher at least in my
22 world. If I'm thinking about sex, if I'm

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1 interested, if I'm aroused it is going to be a
2 much more fulfilling experience that if I'm going
3 along because I was doing the dishes and I can
4 figure out how to make time for it.

5 DR. EGGERS: Okay.

6 BEVERLY: And so that just depends on
7 how you are being impacted by the arousal issue
8 and interest issue.

9 DR. EGGERS: Okay. Does anyone -- does
10 Beverly's point resonate with you?

11 Okay.

12 Any final -- anyone want to build upon
13 that?

14 Go ahead, yes.

15 LEONORE: I think that Beverly's
16 experience is idiosyncratic to her, not unique,
17 but I think other people expect that when they
18 respond but don't initiate that there will be
19 longer foreplay and that if that has been
20 communicated with their partner the foreplay will
21 be choreographed to fit the situation.

22 DR. EGGERS: Thank you. I think there

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1 were a couple of hands over here.

2 KATHERINE: Hi, I'm Katherine. I don't
3 want to say this really because my husband is
4 sitting right next to me but I can tell you that
5 when he does initiate my response is kind of
6 sigh] and that is both mentally and physically.
7 My body really doesn't do anything and nothing
8 happens to me mentally or emotionally either. And
9 I actually don't ever initiate sexual activity
10 since this happened so it is kind of hard for me
11 to answer your follow-up question to that.

12 DR. EGGERS: Is it hard for others to
13 answer the follow up question, like Katherine
14 said?

15 Go ahead Victoria.

16 VICTORIA: I have to say I 100 percent
17 relate to what she just said and I felt the same
18 way. When you asked that question I was kind of
19 going I never initiate so I don't even know
20 anymore.

21 DR. EGGERS: This -- what makes the
22 questions that we are asking difficult for you is

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1 as much as we want to know what the answer to the
2 question is. So please feel free if we are asking
3 the questions in the wrong way you can alter them
4 to fit your experience, so feel free.

5 We have a hand right here.

6 CARMON: Hi, my name is Carmon and my
7 trip was funded by Veritas but like Beverly I
8 would have flown here without that. I am really
9 excited that you are doing this.

10 My husband and I have suffered for over
11 30 years with my low libido and I did get
12 treatment which has helped me tremendously. And
13 for the first time in a long, long time I do
14 initiate sex sometimes. And for my husband that
15 is a wonderful blessing because he knows that it
16 is not duty sex but that I actually want him. And
17 he wants me to want him. And I think that most
18 partners feel that way about their sexual
19 relationships. So it does make a big difference
20 that I'm able to do that now.

21 DR. EGGERS: Thank you.

22 Who else? Here.

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1 SUE: It is Sue again. I think one of
2 the problems that I know occurs for me is that
3 even if I'm willing when my husband initiates to
4 have sex I can't stay in the moment necessarily
5 and then your body stops responding. And even
6 going into the bedroom is like am I going to stay
7 focused today, am I going to have an orgasm today.
8 It is like you feel sometimes like why waste your
9 time having sex if nothing is going to happen but
10 say okay I'm willing to try again, I love my
11 husband. Essentially it starts out being duty sex
12 and if you are lucky it turns into great sex. I'm
13 in my 60s and sometimes sex is the best it has
14 ever been in my life because like some of these
15 other women my children are grown so I don't have
16 those kinds of stressors. But sometimes my body
17 just betrays me and it doesn't respond or it
18 responds but then if I can't stay in the moment
19 and I've taught myself to refocus back, sort of my
20 own version of mindfulness. But it doesn't always
21 work. And that is a really hard issue to deal
22 with. And there are times that like Beverly when

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1 my -- I have a testosterone pellet and when it is
2 fresher and newer my body -- I am more interested
3 and when it is getting later my husband can also
4 tell. He goes, go get your blood test; it is
5 probably time for a new pellet. And we never know
6 when we can count on our minds and our bodies.

7 DR. EGGERS: Thank you Sue.

8 One more right here and then -- oh, we
9 will do two more. One more right here and then
10 one more in the back.

11 AMANDA: Hi, I'm Amanda and likewise I
12 signed up to be part of this discussion before I
13 found out that my travel could be funded by
14 Veritas. But in response to the question I agree
15 with what everybody said. Obligatory sex is a far
16 cry from initiating and I think for years the
17 burden of a healthy or a regular sexual
18 relationship has fallen on the men particularly my
19 husband. And I think that they've sort of got the
20 bum rap and women have too. But unfortunately in
21 the lack of desire that is what it falls down to.
22 So in the short amount of time that I was treated

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1 it made a dramatic difference for us as far as my
2 initiating and I can tell that it definitely
3 elevated our whole level of intimacy and the way
4 we related to each other. Once I stopped it
5 returned to normal and unfortunately the burden
6 falls in his shoes. But I think it would be
7 interesting one day if you guys could pull some
8 men and get their thoughts on the process.

9 DR. EGGERS: All right. Thank you.

10 Okay. One more back there?

11 THEA: Hi, my name is Thea. I have no
12 funding to be here. I know for myself and many of
13 my friends growing up we sort of learned not to
14 initiate sex because some of our boyfriends made
15 fun of us or I know there is a stereotype that men
16 are always wanting sex but that wasn't always my
17 experience. And also it took us longer to orgasm
18 and we found that embarrassing and wondered if we
19 were normal because in porn, in culture, in
20 Hollywood movies it seemed very easy for women.
21 So there was a lot of shame around that.

22 DR. EGGERS: Thank you very much. Leah,

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1 right? Thank you
2 Let's move on to the next question that focuses on
3 arousal. For those of you who experience absent
4 or reduced sexual arousal which of the following
5 affects do you consider to have the most
6 significant impact on your daily life? And here
7 again you can choose up to two. No or reduced
8 sexual excitement pleasure during sexual activity?
9 No or reduced sexual arousal in response to
10 written, verbal or visual cues? No or reduced
11 genital or non genital sensation during sexual
12 activity? Or other?

13 Okay. So the top two in terms of
14 frequency here no or reduced sexual excitement or
15 pleasure or no or reduced genital or non genital
16 sensation during sexual activity.

17 On the Web can we get a sense of what
18 the responses were?

19 MS. GIAMBONE: Sure. 50 percent of the
20 people on the Web said no or reduced sexual
21 excitement or pleasure during sexual activity. 40
22 percent said no or reduced sexual arousal in

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1 response to written, verbal, or visual cues.

2 Followed by 30 percent with or reduced genital or
3 non genital sensation. And then ten percent said
4 other.

5 DR. EGGERS: Okay. If you are on the Web
6 it sounds like a few more of you talked about
7 arousal in response to written, verbal or visual
8 cues. Send in - - type in a comment to that.

9 On the Web did I ask about what the
10 responses -- did they look similar to that first
11 question I asked?

12 MS. GIAMGONE: Yes, very much so.

13 DR. EGGERS: Very similar. Okay. So
14 let's go into a little bit of these issues in a
15 little bit more depth. How do you differentiate
16 between the terms excitement, pleasure, sensation,
17 arousal? Do you tend to use -- do they mean very
18 similar things for you? Do you prefer one term?
19 Does one term arousal or excitement or a different
20 term resonate for you?

21 We will go with Karen first.

22 KAREN: I forgot to disclose that I have

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1 not received any remuneration of any type to be
2 here.

3 I think in my opinion that question is
4 incredibly varied and everyone is going to be
5 using a different word to describe what is either
6 psychological or physical. Excitement, arousal I
7 mean pick a, b, c or d.

8 DR. EGGERS: Then can I follow up. Does
9 it make it difficult to answer these questions and
10 identify which one of these would be most
11 important to you given that they all use different
12 terms?

13 Following up on what Karen said. I see
14 some head nodding.

15 So if I ask about the sexual excitement
16 and pleasure during sexual activity would someone
17 be brave enough to explain what are you
18 conceptualizing when you did respond to that one?
19 Is it the sensations? Does it include orgasm? You
20 know this is a very tough subject to address and
21 so we do appreciate all of your thoughts and
22 experiences.

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1 Well if you do want to comment on that
2 and work it in somehow, feel free because we do
3 know it is difficult as Karen was saying.

4 Sure go ahead.

5 LOUANNE: I'm Louanne and I am a patient
6 and I am also a therapist. And my travel was paid
7 for by Veritas.

8 The way I look at it from the therapist
9 mindset sexual excitement is what you make out of
10 what your body is feeling. But sensation is what
11 you actually believe you are feeling and it is the
12 transmission of the nervous impulses that you go,
13 oh, I feel that, it is muted; it's less than I
14 felt before but I feel that. And then I think a)
15 is what you make of what you are feeling and how
16 pleasurable you categorize it for yourself.

17 DR. EGGERS: Okay. Thank you. Anyone
18 else want to comment?

19 Yeah, right here.

20 DR. PARISH: So my name is Dr. Sharon
21 Parish. I'm President of the International
22 Society for the Study of Women's Sexual Health and

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1 my travel was supported by SPROUT.

2 I think looking at the distribution of
3 responses here. I think it is very important to
4 understand the age range of the women both in the
5 teleconference and also in the room. And c) is
6 going to be very different in a younger versus an
7 older woman. And I think this differentiation in
8 understanding these responses is very critical to
9 understanding this diagnosis in patients here and
10 in our offices.

11 DR. EGGERS: Do the FDA colleagues want
12 to follow up on any aspects of what we've been
13 talking about interest or arousal?

14 Yes, Christy.

15 DR. CHANG: I have a question on
16 response b) actually. So even though it didn't
17 get as many votes as either a) or c) I'm just
18 wondering if any of the ladies could clarify for
19 us what kind of written cues, verbal cues, visual
20 cues or even tactile cues may help in helping to
21 reduce the difficulty with arousal?

22 DR. EGGERS: Okay. We'll go with Karen.

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1 KAREN: Well as a sexuality educator I
2 am very interested in finding ways to become the
3 best lover you can become. And for some people
4 that is looking at erotica. For some people in
5 response to your question that is using sex toys
6 of all kinds, either alone or with your partner.
7 It is so again varied in the ways that you can
8 besides just being anxious about it that you can
9 learn to be a good lover and to accept the limits
10 of what you are able to achieve or accomplish
11 without feeling like a failure.

12 DR. EGGERS: Does anyone else have
13 another follow up. We have one here.

14 NATALIE: Hi, my name is Natalie. I
15 received a travel stipend to be here today as well
16 from Veritas --

17 DR. EGGERS: Can you talk a little
18 closer to the mic. Thank you.

19 NATALIE: I have a thought about arousal
20 and desire that occurs to me. I used to have a
21 normal sex life my whole life and then this
22 happened. It was a year of going through hell but

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1 I am now being successfully treated. And so the
2 question about desire is basically before -- it is
3 not a matter of how much foreplay we do or not.
4 I'll be approached and we can spend forever trying
5 to make something happen. And the difference is
6 the desire within me. It is very obvious for men
7 when it is working and not because they are able
8 to have sex. I am able to grit through it which I
9 often do in terms of like I do it for him but not
10 for me. So the loss of the desire is what I think
11 it is important to make that distinction. It used
12 to be there. It is not anymore unless I keep
13 getting treated every four to six months.

14 DR. EGGERS: Thank you very much.

15 Yes. Sandy.

16 DR. KWEDER: If it is okay can I probe
17 one of the responses.

18 DR. EGGERS: Oh, of course.

19 DR. KWEDER: I can't see the woman who
20 is the head of the society, there you are. Can
21 you say a little bit -- can you expand a little
22 bit on the comment that you made about some of the

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1 differences you might expect or expectations for
2 some of these responses based on age range. Can
3 you comment on that a little bit?

4 DR. PARISH: Sure. Absolutely. So I
5 was referring to item c) no or reduced genital or
6 non genital sensation during sexual activity. You
7 know both organic diseases that are sometimes co
8 morbid with older women such as diabetes,
9 hypertension and other neurologic conditions or
10 genital symptoms of menopause related to vulvar
11 and vestibular changes may result in changes in
12 genital and non genital sensation during sexual
13 activity. So I think looking at the spectrum of
14 responses has to be in the context of
15 understanding we have a distribution of ages of
16 women in the room and it might be useful to
17 separate that out.

18 DR. EGGERS: Yes, Marcea?

19 MS. WHITTAKER: I have a question and
20 Sara actually asked it and I think it is important
21 as we move forward. The question was when we
22 think about excitement and pleasure and arousal

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1 does that include orgasm. And so we can maybe
2 just do a show or hands.

3 DR. EGGERS: Sure. So if in those set
4 of terms you would include orgasm could you please
5 raise your hand if you feel comfortable.

6 Okay.

7 If that term doesn't need to be there,
8 is not included in that, I'll assume the rest of
9 you? Raise your hand.

10 It does not need to be; is not a part of
11 that? It can be but doesn't have to be; raise
12 your hand please.

13 Okay. Seems like a majority. Thanks
14 for clarifying.

15 I wonder if we can go back to this
16 question here about the age range. Can I ask how
17 many people who indicated c) about the sensation -
18 - I have to do some math here -- how many of you
19 are 40 and less? Let's take 51 and older? How
20 many of you answered c)?

21 Okay. And younger than 51?

22 Okay. So we obviously don't have

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1 exactly the spread but it does say that there is a
2 difference. At the break we'll try to see what the
3 clicker responses were and go back. We might mess
4 up some technology here. We are kind of one
5 direction.

6 DR. MODJOROS: Hello, my name is Melanie
7 Modjoros. I'm a physician and a sex therapist in
8 northern Virginia. I have no financial interest
9 to disclose.

10 And I think this is a very interesting
11 question. Every woman conceptualizes it a little
12 bit differently. From my patients sexual
13 excitement is often akin to the building of an
14 orgasm but not necessarily the actual orgasm.
15 Sexual pleasure is usually included in that
16 building but, of course, the pinnacle is the
17 orgasm and the climax that most men and women are
18 looking for.

19 The sexual arousal in response to
20 written, verbal, and visual cues can be in a solo
21 setting or in a couple setting. And that is
22 different because if a woman hears and I've heard

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1 this from my patients, if a woman hears her
2 husband say something sexy or naughty in her ear
3 that may turn her on. That may result in arousal
4 instantly or not instantly and that may change and
5 that may cause distress.

6 So these answers are very heavy. They
7 are very dense. And teasing it out even more I
8 think would be helpful because every woman
9 experiences it a little bit differently and every
10 woman and couple conceptualizes it differently.

11 DR. EGGERS: Okay. We can take a couple
12 more and then we will move on. But while we are
13 getting the mics over there I'll encourage
14 everyone, I think my colleagues would agree to
15 write about this in the Docket. Write about how
16 you make those distinctions and you can really
17 expand upon it there. That would be very helpful.

18 We will take one more and then we will
19 move on to other symptoms.

20 UNIDENTIFIED PERSON: When you asked the
21 question about do we include orgasm in the concept
22 of sexual pleasure, I think you got few answers

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1 because we were confused by the question a little
2 bit.

3 DR. EGGERS: Okay.

4 UNIDENTIFIED PERSON: And then someone
5 added in well it doesn't have to always happen, it
6 can be included and I think that is a very dense
7 question that needs to be teased out to because it
8 winds up that if a woman has never had an orgasm
9 it is a bit like going to a movie and always
10 leaving ten minutes before the movie ends. And
11 after a while you stop wanting to go to the
12 movies. And so for some people who know that
13 orgasm is an option and it is an option that they
14 can have relatively easily then it is not as
15 crucial of a factor. But when it is never a
16 factor then it is a very crucial one. So I think
17 we kind of blended all of that together when we
18 were raising our hands about that.

19 DR. EGGERS: Okay. Thank you. Thank you
20 for the clarification.

21 Let's move on to other symptoms that are
22 beyond arousal and interest. And then we are

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1 going to be following up on sort of the sexual
2 event. So we are going to be coming back to that.

3 There were some others in both of these
4 categories. Actually let me -- I'm going to give
5 a shout out to the folks on the Web. Before we
6 get into other symptoms is there a brief summary
7 we can have of comments on interest our arousal
8 from the Web?

9 MS. GIAMBONE: We haven't heard too much
10 on the symptoms. We've heard more impacts coming
11 through.

12 DR. EGGERS: Okay. We'll wait for
13 impacts at the end.

14 MS. GIAMBONE: Sure.

15 DR. EGGERS: Now let's talk about other
16 symptoms. What was included in your other?
17 Anyone willing to share that?

18 Okay. Just so we can tease out some of
19 the other aspects of FSD that you might have, can
20 I have a show of hands again for how many
21 experience something other than -- you have
22 interest and arousal challenges but you also have

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1 one of the other aspects of FSD, pain or orgasm or
2 headaches or something else?

3 Would you like to expand upon yours a
4 little bit Carla?

5 MS. PRICE: I'm Carla Price and I failed
6 to mention that I am funded through Veritas but I
7 would have come otherwise.

8 My problem is coital headaches, so as my
9 arousal builds often times I experience just an
10 unbelievable migraine that is worse than any
11 migraine I've ever experienced. So it doesn't
12 happen all the time but more often than not, so
13 some of my low libido might just be the fact that
14 there is pain waiting at the end. So it is
15 painful pleasure I guess you might say. So it's
16 not real fun.

17 DR. EGGERS: And Carla if I might follow
18 up a little bit then. If your headaches did not -
19 - if there is ever a time when your headaches do
20 not accompany your sexual experience, is your
21 interest and arousal still affected? Does it
22 return?

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1 MS. PRICE: No. I actually have to say
2 that I still have a decrease in arousal. The one
3 thing that -- I have been treated a little bit and
4 it has helped about 50 percent but again the
5 arousal -- the desire seems to be an issue. Which
6 I do want to add I like the comment I would love
7 to look at the husbands and partners views. It
8 has come to the point where my husband doesn't
9 even want to initiate sex because he is afraid
10 that he will hurt me because of my headaches. So
11 he said what fun is it for me to cause you such
12 pain. And so our marriage and relationship has
13 been really rocky. And it is -- I mean it has
14 affected his self-esteem and his manhood. So it
15 is definitely a domino effect.

16 DR. EGGERS: Thank you, Carla.

17 So I think we have another opportunity
18 for the Docket comments which is to ask your
19 husbands to submit -- your partners to submit a
20 comment, invite them to. We would like to hear
21 from men as well on their perspectives on this.

22 Would anyone else like to talk about any

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1 other symptoms particularly as they relate to or
2 how they affect interest and arousal?

3 We have Beverly and then we'll go back
4 there.

5 BEVERLY: I just want to say that I
6 don't know if these are all physical things and so
7 if I'm reading the question most significant
8 impact on your daily life and I covered that a
9 little bit when I was speaking because I think
10 there is a whole myriad of other things that it
11 affects. Most often it affects things like my
12 self confidence and how I approach the world and
13 how I feel about myself and what I project to
14 other people. So I don't know if anybody is
15 thinking about that because the multiple choice
16 answers that you offered were really so specific
17 to being aroused or to being interested or actual
18 intercourse.

19 And I think that other category can take
20 into account a whole lot of other things that I'm
21 sure a lot of women in this room experience. But
22 we are so focused on how it actually works with

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1 actual sex act that it is not -- they are not
2 bringing in this whole other area.

3 DR. EGGERS: Okay. So maybe I'll go a
4 little bit astray on this and say if you knew that
5 anxiety could have been one of your choices, how
6 many of you would have put anxiety as it was
7 described. Someone described anxiety here. How
8 many of you would have put that in your top two?

9 Okay. Several. And we had -- we did
10 hear about it earlier is your experience the same
11 as what we heard about which is a physical anxiety
12 that happens when you think about desire or when
13 you think about arousal or when initiation
14 happens?

15 BEVERLY: The problem with that too is
16 when you take that to any physician and you tell
17 them you have anxiety or you are depressed about
18 it, they give you an anti-depressant which then
19 inhibits your desire and inhibits your ability to
20 orgasm. And so it ends up becoming a circle.

21 DR. EGGERS: Okay. Great.

22 I do want to go back there; there was a

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1 comment back there.

2 JUDY: Hi. My name is Judy. And the
3 Social Sciences and Humanities Research Council of
4 Canada paid for my trip. I'm here as a
5 researcher.

6 But my research is on language in
7 particular, and in particular language relating to
8 health, medical conditions and this one in
9 particular which I've studied for a while. I
10 find it interesting how central the language of
11 symptoms is. And it is a word that you keep using.
12 And I think that the idea that these are symptoms
13 suggests that there is an underlying disease and
14 that that is kind of the position that we are
15 starting from even though we are talking about
16 variety and experience and the DSM criteria are
17 kind of more open than that in fact. And so I
18 wonder what would happen if we stop using the
19 language of symptoms to talk about everything
20 we're experiencing.

21 DR. EGGERS: Would it be better for the
22 purpose of discussion if we used the term aspects,

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1 that should cover everything, so I'll try to use
2 that term moving forward; can't promise it. But
3 I'll if I think of it I'll try to use that term.
4 It sounds like that is a more appropriate term.

5 Are there any other aspects of interest
6 and arousal that FDA wants to follow up on?

7 MR. JOFFE: I had one question. I think
8 it has come from a few people that treatment can
9 kind of make some of the arousal and desire wax
10 and wane. But I was wondering for those of you
11 who maybe aren't on treatment or even those on
12 treatment could separate it, trying to get a sense
13 of what arousal and desire is doing in general.
14 Is there a waxing and waning over time or do you
15 feel it is kind of a steady state of where you are
16 all the time with this condition?

17 DR. EGGERS: We will go with Vicki
18 first.

19 VICTORIA: I had treatment when I first
20 went to see Dr. Goldstein he did -- I got the
21 testosterone pellet and it did work like some of
22 these women are saying for a short period of time.

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1 But it wasn't in my budget to keep going back and
2 flying back to see him and it wasn't offered where
3 I live. So I am currently not on any treatment.
4 And I -- when I was on the treatment it helped a
5 little bit. And now I am just back where I
6 started and my symptoms are pretty constant and
7 they don't wax and wane. It is the same every
8 day.

9 DR. EGGERS: Can I get a show of hands
10 for how many people share the same experience as
11 Victoria?

12 Okay.

13 Karen did you want to follow up on that?

14 KAREN: Well I guess it is again and my
15 role as a sexuality educator that the way that can
16 be dealt with these things is to enlarge your
17 perspective beyond the -- as I call it in my
18 classes, the stairway to heaven -- [Laughter]

19 KAREN: -- which is a lockstep way of
20 going and getting to the ultimate orgasm. And
21 there are from personal experience a lot of outer
22 course sensuality based communications and

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1 experiences with your partner that can reduce the
2 anxiety and the pressure of having to go all the
3 way to the top.

4 DR. EGGERS: Okay. Thank you.

5 We will be revisiting this in more depth
6 in the next discussion about treatments in
7 general.

8 I want to tee up the phone to see if
9 there is anyone in particular on the phone who
10 absent treatment you experience waxing and waning
11 of symptoms; that would be useful to hear about.

12 Did anyone -- we asked about absence of
13 treatment, no waxing and waning or a constant
14 symptom, is there anyone who does experience a
15 waxing and waning of -- sorry, aspects, of their
16 condition over time. Okay. In the back there.

17 THEA: Sorry, I mean I think that it is
18 fair to say that desire waxes and wanes as a
19 normal state of human physiology and being. I'm
20 also a sex researcher and that is what all of the
21 evidence points to.

22 DR. EGGERS: Does anyone have an

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1 experience they can use to illustrate that?

2 SUE: I think one of the confounding

3 facts of that question is a lot of us are on

4 therapies that are not constant. If you are

5 taking a daily testosterone gel for instance it is

6 relatively constant whereas if you are using a

7 pellet it forces the waxing and waning. But I

8 think in addition that for some of us who are

9 older things change as well. I know I interviewed

10 a lot of women for a book I wrote and one of the

11 women said it was like a light switch turned off.

12 She just lost all interest, all desire; and it

13 didn't change whereas for me it was something that

14 happened slowly over time and then for me with

15 time for treatment I was better and now as I am

16 getting older I have been on treatment for 13

17 years, I was diagnosed 13 years ago and now I find

18 that testosterone alone isn't enough. I have

19 changed. But it is not a daily waxing and waning

20 per se but it is a slow change so I think we

21 really have two kinds of patients; those who just

22 one day everything changed. I think Vicki said it

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1 after her fourth child everything just totally
2 changed whereas for some of us it is a slower
3 progression.

4 DR. EGGERS: Thank you very much.
5 Go ahead, right there?

6 MS. KINGSBERG: Will all due respect to
7 the normalcy of desire -- I'm Sheryl Kingsberg;
8 I'm a psychologist and professor in reproductive
9 biology at Case Western Reserve. I think the
10 premise of this whole meeting is about an unmet
11 medical need and that we've all agreed that this
12 is a condition that we are working to find
13 treatments for. So I think symptom is appropriate
14 and I think it does a disservice to the women who
15 have come all this way to talk about their
16 condition and their symptoms to be respectful of
17 that. That this is really very distressing.

18 DR. EGGERS: Right here. Yeah, if you
19 could state your name and indicate -- there was a
20 hand right here. And make your disclosure please.

21 BEN: Yes, thank you. My name is Ben
22 and I'm here with my wife. Veritas did pay for our

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1 travel. This is an issue that is very important to
2 us. A couple of people have mentioned the impact
3 on the man in the relationship and I can speak
4 from personal experience. And it does have a huge
5 impact when your lover, your soul mate is no
6 longer interested in having sex with you. We've
7 experienced the waxing and waning but it
8 definitely affects the man. Again I know it is
9 primarily about the woman but it affects the man,
10 it certainly affects your ego, how you feel about
11 yourself and it affects the broader relationship.
12 So it has broader implication than just the man
13 and the woman. It actually affects the
14 relationship in the entire family.

15 DR. EGGERS: Thank you.

16 All right. I have a question about
17 symptoms or aspects and their changing over time.
18 We heard mention -- I can't remember -- I don't
19 believe any of you mentioned this but in the
20 comments that were sent to us a few people
21 mentioned keeping a log and a diary, a daily diary
22 every day. Does anyone keep a diary of their

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1 condition?

2 Here, yes, can you explain what you put
3 in your diary?

4 MS. REED-HOFF: Oh, I use a topical.

5 I'm Judith Reed-Hoff (ph) and Veritas handled our
6 travel arrangements, thank you very much.

7 I use a topical EstroGel and Testim and
8 so then I record every day what the volume is that
9 I administer to myself and then when it gets -- I
10 feel out of whack then usually I know it is time
11 to have my blood test done because Dr. Goldstein
12 is very emphatic about following up anywhere. I
13 started off at three to four weeks and now six to
14 eight weeks.

15 DR. EGGERS: So if you were asked to
16 think about tracking your symptoms over time; does
17 anyone track those over time just as a natural
18 thing that you do?

19 You track symptoms, too?

20 JUDITH: Yes, I do, I track symptoms
21 because I think it is important that I know
22 because sometime we think we are feeling okay but

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1 if you write it down it makes a lot more sense and
2 you can look back and say okay this was not a good
3 day or a good evening and then I'm able to know
4 what to do from then on.

5 DR. EGGERS: Was there -- yes, Carol?

6 CAROL: When I was being treated at the
7 beginning of this experiment I kept a diary
8 religiously and I did symptoms every day and the
9 reason I did that was when I went to see my
10 physician we would look for patterns that the
11 symptoms are a lot of times related to the amount,
12 the dosage of medication that you are on. And
13 when you are not on enough you are going to become
14 symptomatic. And when you increase it a little bit
15 it resolves the problem until you get to the next
16 hurdle. So it was very useful for both me and the
17 doctor that treated me.

18 DR. EGGERS: Okay. So I think what we
19 are hearing is that the tracking of symptoms over
20 time is in large part due to finding the right
21 treatment or dose for you. But I imagine the same
22 sort of aspects apply to the question that I'm

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1 going to ask so I am going to ask first I'm going
2 to ask this question.

3 Knowing that you would want to track
4 your symptoms as accurately as possible, how often
5 do you think you would need to report in order to
6 remember those symptoms accurately?

7 Okay. We have very clearly -- well,
8 we've made it clear that this is dependent on if
9 you are on a treatment. But I'm going to ask you
10 to when you answer the question just say whether
11 you are on a treatment or not and answer the
12 question -- anyone to answer the question about
13 what time period do you need. Do you need to
14 record them daily, weekly, monthly, et cetera?

15 We have one hand here and then we will
16 go on to others.

17 AMANDA: I am not currently on a
18 treatment. And I myself at times did keep track of
19 symptoms but what I found unfortunately was daily
20 was not important because to me as time went on it
21 was the broader picture and the longer range and
22 it actually became more depressing and distressing

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1 to think about on a daily basis. It sort of
2 became the new norm which really was not
3 acceptable. So my goal was the long term affect
4 and how it was affecting me.

5 So conversely you have really good
6 sexual experience when I was being treated you
7 don't also need to record that because you don't
8 forget that and especially as few and far between
9 as those occurrences were that was more critical
10 and more important that I track than a daily
11 occurrence because to me it became the new norm.

12 DR. EGGERS: Okay. How many people does
13 it resonate for what Amanda said?

14 Okay. Any different experiences? We
15 have a hand here in the back.

16 LEONORE: You know it's -- we're talking
17 about treatment and we've only been talking about
18 certain kinds of medical treatments. So let me
19 just say that non-medical interventions: psycho-
20 therapeutic intervention, psycho-educational
21 interventions. These also involve a certain amount
22 of paying attention to what is going on in the

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1 relationship and paying attention to what is going
2 on in one's moods and in one's body. But it is
3 done in a completely different way because
4 attentional focus is really reframed in some sex
5 therapy, sex therapy that I do as a problem so
6 that you don't want to get obsessively
7 preoccupied with self monitoring. So I'm finding
8 this conversation a little difficult. If we could
9 talk specifically about medical interventions and
10 how you deal with reduce arousal and paying
11 attention and this and that but it is done quite
12 differently with psycho- therapeutic interventions
13 even though one could pay attention to symptoms or
14 aspects. But one tries to get away from
15 obsessional self focus as the magnifying problem
16 rather than a useful intervention.

17 DR. EGGERS: Okay. I think there was
18 another hand up and I'll turn and see if there are
19 any follow up questions to that. Thank you very
20 much.

21 KATHERINE: I actually had never even
22 thought of the idea of keeping a diary or a log of

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1 my symptoms because as someone mentioned on the
2 other side of the room I was one of the people
3 that had the switch flip in my head. And I had it
4 one day and the next day I didn't.

5 And when I just realized my feelings
6 were kind of always that way I felt no need to
7 write it down because they are the same every
8 single day. There is nothing dynamic. There is no
9 waxing or waning with me. And I'm not on any
10 treatment. So --

11 DR. EGGERS: Thank you very much
12 Katherine.

13 Are there any follow up questions?

14 OPERATOR: We have one question from
15 Maria.

16 DR. EGGERS: Okay. Let's go to the
17 phone.

18 Yes, operator. Yes, Maria, hi.

19 MARIA: Hi. How are you?

20 DR. EGGERS: Very good, thanks.

21 MARIA: Good. I have a question in
22 reference to the treatment from a physician

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1 standpoint. [Garbled.]

2 DR. EGGERS: Maria. Can I interrupt you
3 for a second? Can you hold the phone further
4 away. Let's see if we fix the sound quality.

5 MARIA: Okay. One moment. Is that
6 better?

7 DR. EGGERS: That is better, yes. If
8 you could just briefly recap what you were saying?

9 MARIA: One moment. I will take it.
10 Can you hear me?

11 DR. EGGERS: Yes.

12 OPERATOR: Much better.

13 MARIA: Okay. Great. I was saying that
14 when I was treated, I recently had BioTE which are
15 the pellets done. And I had to actually change
16 physicians because my OB Gynecologist, the doctor
17 I had been going to for the last 50 years did not
18 agree with the actual treatment due to the
19 information that had been submitted to them of the
20 year in terms of the danger and why wouldn't --
21 and all of the information that comes across I
22 think that our practitioners are well informed. I

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1 gave my practitioner with information and I am
2 just like looking over the Internet. How can I
3 fix my problem? I am like when is in Vitro coming
4 out? Why can't Flibanserin -- why can't those
5 drugs be approved? What is the issue? I mean my
6 depression --

7 DR. EGGERS: Hey, Maria, I am going to
8 interrupt you at this point because we are going
9 to be talking about those issues in our afternoon
10 discussion. Did you have anything that you would
11 like to contribute about the symptoms you feel
12 particularly as they change over time?

13 MARIA: Yes.

14 DR. EGGERS: Okay. Thank you.

15 MARIA: My vaginal dryness is there. I
16 didn't use to have that issue at all. In terms of
17 anxiety building up with the thought of sex that
18 has increased immensely which is a deterrent for
19 me having sex and a deterrent for my husband
20 fulfilling sex.

21 DR. EGGERS: Okay. Thank you very much.

22 MARIA: Okay.

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1 DR. EGGERS: Do we have one more person
2 on the phone? No. No we don't. Okay.

3 We have a few more minutes. And let's
4 first see if there is any Web comments that have
5 come in particularly on the ideas that we've been
6 talking about changing or not changing over time.

7 MS. GIAMBONE: So we have heard a few
8 symptoms mentioned; disinterest, repulsion,
9 intense pain that has brought tears. And then in
10 terms of changing over time one participant
11 commented that for her the challenges were in the
12 beginning of her sexual experience and then
13 sometimes the challenge would be reaching an
14 orgasm so that it varies throughout the
15 experience. And then other factors, we heard a
16 few factors on feeling guilty and feeling as
17 though their partner felt as a failure that they
18 couldn't please -- satisfy.

19 DR. EGGERS: Thank you.

20 I want to ask a few questions about
21 engaging in sexual activity. We've talked about
22 that some. But I have a few directed questions

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1 about that.

2 So if you were asked to rate whether
3 your last sexual event was satisfactory or not
4 satisfactory what would go into this
5 determination? I realize this is a very hard
6 question so you can change the question if you
7 need to. But what we want to know is what goes
8 into a determination of whether a particular
9 sexual event, however -- you've determined that
10 you've had sex of some sort. How do you determine
11 whether that is satisfactory or not to you? What
12 factors into that?

13 Okay. Karen, please.

14 KAREN: Well it depends on what your
15 expectations are for the outcome.

16 MS. EGGERS: So your expectations. Have
17 you expectations -- show of hands if your
18 expectations now on what you would consider a
19 satisfactory sexual event has changed than when
20 before this happened?

21 Show of hands? Okay. So within this
22 new set of expectations is it easy to tell whether

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1 a sexual event was satisfactory or not?

2 Katherine I don't want to pick on your
3 but I see you might have something to say.

4 KATHERINE: It is a success if he is
5 having a good time because it is out of obligation
6 for me and I have no expectations. I might not
7 even want to have sex but if he wants sex then and
8 I give it to him then, yes, I was a good wife
9 today.

10 DR. EGGERS: Does that resonate with
11 others?

12 We have one comment here and then we
13 will go to the back.

14 MS. MODJOROS: As a sex therapist I deal
15 with the idea of satisfaction a lot and
16 satisfactory sex. I would say that the majority
17 of my patients that is not the goal. They are not
18 looking for satisfactory sex. But if you ask them
19 specifically what it is that they would find
20 satisfactory sometimes you get incredibly sad
21 answers. Like a woman who says she doesn't want
22 to cry after sex. A man who says I just want to

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1 feel desired. And so looking for satisfactory
2 sexual experience I think it is not the goal of
3 the average adult. And I don't know that it
4 should necessarily be the goal that we are looking
5 for either. Probably satisfying, not satisfactory
6 but satisfying sex and good sex and where emotions
7 are pleasant afterwards would be a better goal at
8 least for the patients I see.

9 DR. EGGERS: As a follow up I'm going to
10 ask a show of hands. To follow up on this a show
11 of hands if achieving a satisfactory sexual event
12 is a meaningful aspect of your overall condition?

13 Okay. So it looks like for several of
14 you that is true.

15 There were a couple of hands raised over
16 here.

17 MS. WATSON: I'm Lauri Watson and I'm a
18 sex therapist. I paid for my own travel.

19 I think that when women tell me, I've
20 treated at this point hundreds and probably
21 thousands of women with low sexual desire, and
22 when they talk about what is satisfying it isn't

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1 just necessarily an orgasm, although I think that
2 is hard to understand if the goal is orgasm for
3 perhaps a male partner, they'll say yes, I got
4 aroused, I reached an orgasm. But what is
5 missing for them and I'd like to split apart again
6 desire and arousal. What is missing is they
7 didn't necessarily want it. They didn't desire it
8 in the first place. And that is subjective sense
9 of desire is often very missing and feels
10 difficult for them.

11 Thank you.

12 DR. EGGERS: One more over there.

13 KELLY: My name is Kelly. And I paid
14 for my own travel. I agree with the two ladies
15 here. It is -- there is no wanting to have sex.
16 There is no -- and it is very difficult when you
17 do have it it is out of obligation whether you
18 want to admit to it or not. And it is difficult
19 that it is. And I would say something that would
20 end up being pleasurable would be the fact that
21 when it ends your husband doesn't automatically
22 think it was out of obligation. And it is

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1 difficult, as the gentleman said, it is difficult
2 for everybody. It doesn't just affect the female.
3 It affects the male and their mental state which
4 affects your relationship which affects how you
5 deal with your kids and it affects how you deal
6 with everybody else and how you think of yourself.
7 It is an encompassing thing and to have to try to
8 write it down every day is discouraging and
9 depressing. So I think -- I know that kind of
10 answered a bunch of different questions.

11 DR. EGGER: Karen and then we will go to
12 Amanda and then I have a follow -- I have one wrap
13 up question.

14 KAREN: Are any of you aware of the
15 faked orgasm?

16 [Laughter]

17 DR. EGGERS: That was a rhetorical
18 question.

19 KAREN: Well the laughter in the room
20 sort of indicates that it is a phenomenon for all
21 women to want to please their partner or think
22 that their partner wants them to have this

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1 orgasmic nirvana kind of feeling. It makes me
2 wonder how many partners have actually talked to
3 each other either at the beginning of a
4 relationship or during their relationship about
5 what pleasure they would like to have and how they
6 can give it to each other. And for some people
7 outer- course is much more pleasurable than
8 intercourse and the discussion here has been
9 focusing on intercourse and orgasm.

10 DR. EGGERS: Thank you.

11 KAREN: But how do you know what really
12 pleases your partner most. It may not be that
13 cultural stereotype, again as I've been commenting
14 on that orgasm is not the necessary goal for all
15 people.

16 DR. EGGERS: I will just reiterate that
17 the Docket is -- it would be a great place to --
18 we would like to hear across the spectrum about
19 what your goals are in your sexuality, your sexual
20 experience. So I'll encourage you to contribute a
21 Docket comment and include that.

22 We'll go to Amanda and then I have one

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1 question to wrap up.

2 AMANDA: I agree with what Karen was
3 saying in that for me sex is not just about
4 orgasm. I mean a successful or satisfying event
5 for me is more about feeling connected to Ben and
6 being close and feeling arousal. But it is also
7 on the desire component of it is that I can have
8 sex, it is not an issue being able to have sex
9 because I can perform any time. The difference in
10 desire is that comes from within and that makes me
11 feel alive and like a woman and desirable and
12 feminine and that is the aspect I think I bring to
13 Ben when I'm feeling that which is not very often
14 and so I think that is the difference between a
15 satisfying sexual event that has desire
16 accompanied with it because I feel like I am
17 contributing.

18 DR. EGGERS: Great. And I see some head
19 nodding.

20 We will go to the Web. Are there any
21 final comments particularly ones that haven't
22 touched upon something not addressed yet?

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1 MS. GIAMBONE: We did hear a few
2 participants comment on factors that they felt
3 have led to their FSD including age, body image,
4 boredom and then another participant commented on
5 having more research on attitudes on sexual
6 behavior specifically for residents in nursing or
7 non nursing home settings. And finally we had one
8 other comment on one participant commented that
9 she has to pretend to enjoy it for her husband.

10 DR. EGGERS: Thank you.

11 It is very clear that coming up with
12 questions to appropriately ask on such a
13 challenging and personal and variable condition is
14 difficult. So I am going to put a thing out for
15 the Docket, too. If there -- if you are writing a
16 Docket comment and you are like oh, I wish this
17 questions would be asked or this is how you would
18 have gotten really good thoughts about what is
19 most significant to women's lives. Here is a
20 question I'd ask. That would be very helpful. I
21 think it would help FDA as we think about
22 furthering moving forward and asking women

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1 questions about this very personal tough subject.

2 So with that I'm going to say that we
3 are finished with Topic 1 on the most significant
4 symptoms. We are going to be into Topic 2.

5 Let's come back at 2:35. But before you
6 -- can everyone in the audience give a round of
7 applause to all of the women and men who shared
8 their experiences.

9 [Applause.]

10 DR. EGGERS: Thank you so much. We'll
11 be back at 2:35.

12 (WHEREUPON, a break was taken.)

13 DR. EGGERS: I am going to ask you to
14 please make your way to your seats and the Topic 2
15 participants if you could please make your way to
16 the panel table.

17 Okay. All right. This is your last
18 call to make it to your seats, please. We do want
19 to make sure we have a rich discussion two.

20 And again as we get ready for discussion
21 two I am going to ask the discussion two panel
22 members to come up.

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1 Okay. Any of the other Panel 2
2 discussants? Okay. Thank you.

3 As we work our way in I'll just recap
4 the bridge between Topic 1 and Topic 2. We had a
5 very rich discussion on the complexity of FSD in
6 the previous topic and my colleagues have given me
7 the head nod that we are getting very useful
8 information on that complexity and on what matters
9 to you and what's most significant to you both in
10 your sexual experiences and as we've heard through
11 your comments regarding the distress that you feel
12 with this.

13 So as we move into Topic 2 we're going
14 to focus on current approaches to treating FSD.
15 Again with a particular focus on interest and
16 arousal. We have touched upon some treatment
17 issues already. It is unavoidable to have touched
18 up on that in Topic 1 because they are
19 intertwined, very difficult to untangle. We hope
20 to do that now. And as we go through our comments
21 it is going to be important that we can talk about
22 symptoms on treatment versus off treatment,

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1 whatever that treatment is that you are going to
2 be talking about.

3 So we are looking at what you are
4 currently doing to treat your conditions or
5 symptoms? How well those are addressing the most
6 significant symptoms of your condition. How your
7 treatment regimen has changed over time? I think
8 we've gotten a sense of that. Any downsides? And
9 really importantly we'll save quite a bit of time
10 for this is what would you look for in an ideal
11 treatment for your condition? What symptoms would
12 you most like to target? And what would you
13 consider to be a meaningful improvement in the
14 symptom.

15 And with that thinking about this
16 question number six I know that we all know that
17 specific treatments will be mentioned in the
18 course of this discussion and that is appropriate.
19 We will do so. It is unavoidable to do so.
20 However as I mentioned in the ground rules up
21 front we don't want to focus, this is not a
22 discussion on any particular treatment, the

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1 virtues of it except to see what we can build upon
2 to understand that common ground of drug
3 development. What type of symptoms can treatments
4 address? How meaningful that would be to you?
5 And how you know those differences both in terms
6 of frequency, how many more times you experience
7 desire for example, as well as I'm going to call
8 it the quality of that desire or that arousal; the
9 strength of it or the intensity of it.

10 So as you think about your comments
11 today try to build in those things. Please don't
12 focus on specific treatments just for the sake of
13 that treatment.

14 I'm also going to ask again when you are
15 giving your first, when it is your first time
16 speaking in this topic as well to always state
17 your name and also disclose if you are associated
18 with an organization that has an interest in FSD,
19 if your travel has been sponsored, or if you have
20 significant financial interest in drug development
21 for FSD otherwise.

22 So we have four panelists up front.

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1 Again very similar to what we went through this
2 morning. We are going to listen to these
3 experiences shared. And then we will move into
4 the facilitated discussion on this Topic.

5 So without further adieu we will ask
6 Judith to begin. And you just push your little
7 red microphone and bring that microphone pretty
8 close so we can hear.

9 Thank you very much.

10 JUDITH: First of all I'd like again to
11 thank Veritas for our travel arrangements. I'd
12 like to thank Sara for telling me to change good
13 afternoon to good -- I mean good morning to good
14 afternoon in my introduction. And I'm not
15 affiliated with any other pharmaceutical company
16 or drug company.

17 So my name is Judith. I'm 66 years old
18 and I've been dealing with FSD on and off for 17
19 years. I would like to thank the FDA for their
20 interest in the unmet needs of women. These are
21 exclusively my own thoughts on the subject.

22 I believe I am entitled to and deserving

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1 of a meaningful sexual relationship as are my
2 daughter- in-laws and granddaughters. It is not
3 solely the woman who is affected by this disorder,
4 but her spouse, children, plus people in her
5 social circles and workplace.

6 I'm a breast cancer survivor. I was on
7 HRT when diagnosed in 1996, electively put myself
8 back on HRT after a radiation treatment in '97.
9 When the symptoms became a quality of life issue
10 in 2009 I was diagnosed again with breast cancer a
11 second time, taken off HRT before a double
12 mastectomy in 2010. Within three months the great
13 sex life I had previously enjoyed was gone.

14 I felt anger, cheated when it became
15 apparent that it had disappeared. Symptoms I
16 experiences which had the most negative impact on
17 my life were fatigue, vaginal dryness and painful
18 intercourse. These symptoms continuously awaken
19 me which meant I averaged 45 minutes of sleep a
20 night. I was exhausted. I did not have the
21 energy for intercourse or for anything else. I
22 became irritable. I didn't like living with

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1 myself, never mind how difficult it was for my
2 husband. Mood swings were crazy. I was short
3 tempered, not pleasant to be around contrary to my
4 normal behavior which was upbeat and positive. My
5 libido was low. I knew I wanted to have sex but I
6 had no desire. I refrained. However I love my
7 husband and wanted the closeness, the feeling of
8 well being that comes with the passionate
9 satisfying sexual relationship. My self
10 confidence plummeted. I felt I was less of a
11 woman as I no longer had the sexual appetite that
12 I had previously experienced and enjoyed. I had
13 no desire. It had completely vanished. The
14 vaginal dryness was uncomfortable, penetration was
15 painful and stressful. Having sex was not at all
16 appealing. The pain during intercourse was
17 excruciating. Both my desire and interest were
18 overshadowed by my fear of pain.

19 My husband introduced me to Dr.
20 Goldstein who he had met at the VA. Diagnosis was
21 made after an initial interview, a series of blood
22 tests, questionnaires and a vaginal tour. I was

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1 told that my clitoris was that of a six year old
2 and that my hormone levels were almost non-
3 existent.

4 Here was a doctor who believes in
5 something other than verbal therapy, something
6 tangible, a plan that hopefully would restore my
7 lost sex life. Treatment has been an ongoing
8 process for the last two and a half years.
9 Initially changes in my symptoms would fluctuate
10 from week to week, then month to month depending
11 upon on regulation of my topical medications. I
12 still record topical levels daily. Under Dr.
13 Goldstein's strict monitoring blood tests were
14 initially done every three to four weeks, now
15 every eight to 12.

16 My fatigue is gone as well as the
17 vaginal dryness. I produce sufficient
18 lubrication, desire has increased and intercourse
19 is no longer painful. I once again experience
20 both vaginal, clitoral orgasms. However my desire
21 is still not up to previous levels.

22 Getting the physical body in order was

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1 paramount. Menopause and the aging process still
2 manage to affect both my interest and desires, so
3 therefore ongoing treatment is necessary.

4 I tried various medications until we
5 found which worked best. Currently I am on DHEA,
6 Progesterone, Estradiol and Testosterone
7 Versabase, Estrogel and Testim.

8 I've had sessions with the sex and
9 physical therapist. I did need to adjust the
10 Testosterone dosage when acne worsened.
11 Monitoring my blood test was followed by
12 adjustments made to the Estrogel insuring my count
13 stayed within the required range with someone with
14 my history of breast cancer.

15 Downsides are the costs of the
16 treatments not covered by insurance or Medicare,
17 acne, some increasing facial and body hair. I
18 believe treatments that deal specifically with
19 women's low hormone levels and sexual dysfunction
20 are crucial to our psychological and physical well
21 being.

22 FDA approved medicines that can target

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1 improve and enhance women's sexual function plus
2 be cost effective would be awesome.

3 I personally as well as all other women
4 need the FDA's help in finding a solution to FSD.
5 Thank you.

6 DR. EGGERS: Thank you very much.
7 And now we will go to Katherine.

8 KATHERINE: Hi, I'm Katherine. I'm from
9 Indianapolis, Indiana. I need to thank Veritas
10 Meetings who was given grant by SPROUT among
11 others for covering my basic travel expenses and
12 making it possible for me to be here today.

13 I learned in high school sex Ed that a
14 woman's sexual prime, so to speak, is in her 30s.
15 Yet here I am age 30 and I have no sexual desire
16 whatsoever. Things were very different in my 20s.
17 I had an extremely healthy sexual appetite and a
18 great relationship with my husband.

19 Immediately following the birth of my
20 first son I noticed that I had not a lack of but
21 no libido. Still I gave it time thinking well
22 maybe it is just because you had a baby and you

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1 are still healing. I actually waited a year and a
2 half before finally booking an appointment with my
3 family doctor at the request of my husband.

4 I told my doctor I need something for
5 low libido. What do you have for me? His reply
6 there isn't anything for women with sexual
7 dysfunction but we can put you on an anti-
8 depressant in hopes that being in a generally
9 better mood will help with your libido.

10 [Huge sigh] so I left the office a bit
11 confused. Why wasn't anything available to help
12 me? Is it because I am the only woman in the world
13 dealing with this problem. Surely I must be
14 missing something. I began taking Celexa
15 regularly and saw no improvement. My mood was
16 happy, yes, but I was happily not wanting sex.

17 [Laughter.]

18 I went off of Celexa after three or four months of
19 usage. I didn't have any negative side effects.
20 But if I was only using it to help with my libido
21 and it wasn't working I had no need for it
22 anymore.

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1 I looked at other areas of my life.
2 Could stress be an issue? Maybe my diet, my
3 weight, depression; no because I eat organic
4 fruits and vegetables, I maintain a healthy BMI, I
5 exercise four to five days a week, I live a low
6 stress lifestyle and I am not depressed. I am
7 actually quite the opposite. The only thing to fix
8 in my life is my low libido which is negatively
9 impacting my marriage.

10 So I feel like my body has let me down.
11 I feel like it is out of my control at this point.
12 And I feel like I pulled a bait and switch with my
13 poor husband who is undoubtedly wondering where
14 the old me has run off to.

15 If there were a treatment available for
16 my problem I highly doubt I would care about the
17 side effect of the drug, the pros would far
18 outweigh the cons in this situation.

19 The old me is what I'm after. I want to
20 joke and laugh and flirt. I want to think about
21 sex. I want to initiate sex. I want to have more
22 of it. I want to be the woman my husband married

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1 not too long ago.

2 Thank you.

3 DR. EGGERS: Thank you very much

4 Katherine.

5 And next we'll go to Barbara.

6 BARBARA: Okay. I also want to thank
7 Veritas for supplying the grant so that I could be
8 here to speak to all of you. Although I don't
9 care how much it cost me, I'd be here to speak to
10 all of you believe me.

11 Around 25 years ago I noticed that my
12 sexual desire was decreasing. Within a year it
13 was gone altogether. I felt dead inside. And
14 although I had a wonderful marriage and love my
15 husband very much I have no desire for sex. I
16 felt shame and guilt. And had no idea what was
17 happening. On the rare occasion that we did have
18 sex it was done out of obligation rather than
19 desire. I was embarrassed and reluctant to talk
20 to anyone about it.

21 When I finally summoned the courage to
22 talk to my gynecologist about it he listened but

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1 said he has no solutions to offer. I researched
2 this on my own and found that some people were
3 using Testosterone cream. I was able to try
4 Testosterone cream and after several months there
5 was no change in desire. The only noticeable
6 physical change was significant unwanted hair
7 growth. So I discontinued the cream shortly
8 thereafter.

9 In 2011 I answered an ad for women
10 experiencing low sexual desire. After being
11 evaluated I was diagnosed with HSDD and enrolled
12 in a double blind study conducted by Dr. Irwin
13 Goldstein for a drug Flibanserin. Initially I had
14 no change whatsoever in desire. After a few
15 months I was informed that I had been on the
16 placebo and was asked if I would like to try the
17 real thing. I said yes. I couldn't say it loud
18 enough. And within a couple of weeks my feelings
19 had changed dramatically. I had sexual feelings
20 which I had not felt in many, many years. I was
21 the one initiating sex much to the surprise of my
22 husband and the experiences were very pleasurable.

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1 I also had no negative side effects.

2 Shortly thereafter Dr. Goldstein
3 informed me that the drug had been pulled and the
4 trials discontinued. I was devastated to say the
5 least.

6 After 25 years I had found something
7 that worked and then it was taken away. Without
8 Flibanserin as an option Dr. Goldstein tried a
9 Testosterone pellet, off label, which was inserted
10 via a minor surgical procedure. This caused the
11 same unwanted hair growth and now weight gain but
12 no change in desire to speak of. Had this worked
13 I would have consented to undergo this minor
14 surgery every six months or however long it took.
15 But it did not work.

16 One benefit of this experience is that I
17 am no longer afraid to talk about my condition
18 with friends and family. It is amazing how many
19 women of all ages I talk to that have some degree
20 of HSDD and have been quietly seeking a solution.

21 My husband and I are closer than ever
22 now that he understands what HSDD is and how its

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1 affects have nothing to do with my feelings toward
2 him.

3 I conclude, I'm a nurse, I teach at
4 three local hospitals, I deal with many doctors.
5 Since 2011 I have been talking about HSDD to the
6 doctors taking my classes. So many have patients
7 with HSDD and after hearing my experiences they
8 are extremely interested in having a viable
9 solution for them.

10 I would like to see the FDA approve a
11 treatment so women like men can have a solution
12 for their most common form of sexual dysfunction
13 and not have to go off label or order who knows
14 what from foreign countries.

15 This disorder is real. And we need a
16 solution.

17 Thank you.

18 DR. EGGERS: Thank you very much.

19 And finally we have Susan.

20 SUSAN: Hi. I'm Susan. I am not
21 affiliated with any organization who has paid for
22 my trip here today. But I did contact the New

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1 View Campaign this summer as a way to get my story
2 out. And I heard about this meeting through the
3 New View Campaign. And I don't think I would have
4 heard about this meeting if I hadn't made that
5 call.

6 I'm not currently engaged in the medical
7 world around my condition. So I don't think I
8 would have known about this meeting.

9 I stopped having desire for sex about
10 two years into my now eleven year partnership with
11 my husband. Although I was alarmed it wasn't
12 until about four years later when I lost my orgasm
13 that my attention was capture.

14 Up to this point I had a very narrow
15 view of sexual desire focusing mainly on
16 physicality. I really thought I had lost
17 something. I was resigned to the idea that sex
18 was going to be a drag for the rest of my life.
19 As I began my process I went down some of the
20 common paths of pathology, testing hormones,
21 looking in the DSM, et cetera. My doctor told me
22 that my Testosterone was on the low side of normal

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1 and that I could try experimenting with hormones.
2 I told her I was working on relationship and that
3 I wanted to try that first and not confuse drug
4 therapy with relationship work. She stated she
5 thought that was best; that I could try hormones
6 down the road if I wanted to.

7 Once I decided I didn't want to live a
8 sexually repressed life I started finding
9 information that would be helpful to me. I picked
10 up an old book by David Schnarch called Passionate
11 Marriage that I had laying around. The book
12 helped me to expand on my curiosity and explore my
13 orientation towards sex and desire and find better
14 questions. What is desire? Maybe it is not about
15 a physical feeling. Maybe it is about something
16 entirely different that exists outside the
17 physical realm.

18 My partner and I had done work on
19 ourselves in a therapeutic setting challenging
20 individual issues that worked against us in
21 relationship. We exposed a war between us
22 sexually that had to do with the stereotypical

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1 ideas about men and women that we had personalized
2 to each other. We would bring these ideas to the
3 sexual relationship without verbalizing them thus
4 creating distance and disconnection. We learned
5 through our study of the work by David Schnarch
6 that our sexual problems were a co-created problem
7 in our relationship and that I wasn't the problem.
8 Schnarch's approach helped changed our thinking
9 from pathological to relational.

10 Once I was able to move out of feeling
11 bad about my waning physical desire I relaxed and
12 started a powerful process of learning more deeply
13 about love. I didn't recover physically desirous
14 feeling prior to sex. I had originally thought
15 this was the goal. I was wrong. What I do have
16 is a deep desire for a relationship and that is
17 what drives my desire to be sexual with my
18 husband.

19 The physical experience changed for both
20 of us. Our kiss became connected and deep. My
21 orgasm came back with a quality I hadn't
22 experienced before. Most importantly we now know

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1 sex is relationship and we enjoy the physical
2 contact as a way to interact and be close and
3 connected on a deep intimate level.

4 My partner and I differ in our physical
5 experience of sex. But that is no longer
6 threatening to either of us. Accepting our sexual
7 differences has been part of the whole change.

8 Today when we have problems that arise
9 sexually, instead of looking for something outside
10 the relationship for help, we go to what is going
11 on in our life right now that could be affecting
12 us.

13 My therapist said that whatever is going
14 on in the kitchen is going on in the bedroom.

15 When I think about the downsides to my
16 journey we both were challenged along the way to
17 stay with it. The material that arises is
18 unpredictable and where you are headed is unknown.
19 What kept me going was the immediate and projected
20 and far reaching benefits.

21 It literally changed the way we live,
22 share space, and relate together on a daily basis.

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1 What I would look for in an ideal treatment for my
2 lack of desire is a broader definition of normal
3 sexuality for both sexes. I would appreciate a
4 movement away from a culturally driven definition
5 of normal that creates distress and anxiety in
6 people when they don't think they are living up to
7 an ideal.

8 I think there are all kinds of reasons
9 people don't relax sexually in their relationships
10 and it is much more complex than physical
11 diagnosis and physical treatments.

12 It is my personal opinion that
13 treatments that allow for sexual difference
14 account for the human waxing and waning of
15 physical and sexual desire and arousal and focus
16 on relationship work in general would be most
17 helpful.

18 Where to go from there is more a
19 question for each person than it is finding an
20 answer for all. I feel grateful that there was no
21 shortcut for me. I would never have evolved my
22 consciousness to embrace this much more important

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1 understanding of life and love in relationship.

2 And the work continues.

3 Thank you.

4 MS. EGGERS: Thank you very much.

5 I think I'll save clarifying questions
6 until we get into the discussion given the time.

7 It goes without saying that we owe
8 another round of applause to these women who have
9 so eloquently shared their experiences.

10 [Applause.]

11 They have been -- they really set I think a good
12 foundation for our discussion.

13 Again I am going to ask another show of
14 hands. How many of you heard your experiences
15 reflected in at least one of the panel comments,
16 one of the panelists?

17 Okay.

18 Anyone whose experience differs
19 completely from what you heard?

20 Okay. So it sounds like we've captured
21 generally a sense of the range of experiences that
22 we've had; both the successes and the failures

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1 with treatments and the wide range of
2 perspectives.

3 We are going to start with a polling
4 question that will set the stage to understand
5 what you here in the room and what you on the Web
6 have tried or are currently doing. So I guess we
7 are only focusing on what you are currently doing.

8 So what are you currently doing to treat
9 your condition or its symptoms? And this is a
10 long list, so I'll read it out for you. You can
11 select all that apply. So if you've got your
12 little clickers, please use them. Any
13 prescription medications and for that let's
14 include investigational therapies. Over- the-
15 counter products. And by investigational if
16 you've participated in a clinical trial for a
17 therapy.

18 b) Over-the-counter products, c)
19 physical therapy, massage or acupuncture, d)
20 dietary supplement or dietary changes, e)
21 lifestyle changes such as exercises, avoiding
22 stressful situations, et cetera, behavioral

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1 therapies or couple sex therapy, some other
2 support group would be g). h) If you are doing
3 something else that you don't think fits into one
4 of these categories. Or i) if you are not doing
5 or taking any therapies of any kind. And you
6 can select all that apply.

7 Yes, it is unsurprising that we get a
8 range of many different things. The most
9 prevalent here in the room being the prescription
10 medicines followed closely by the over-the-counter
11 products. We will get into that a little bit. A
12 quarter or you in the room say you are not doing
13 or taking any therapies which is interesting. We
14 might follow up on that a little bit and get your
15 reasons why for that.

16 On the Web?

17 MS. GIAMBONE: On the Web we have about
18 50 percent of the people not doing or taking any
19 therapies. And --

20 DR. EGGERS: I'm sorry, 50 percent?

21 MS. GIAMBONE: Yes. Just about 50
22 percent. And then we also have about 36 percent

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1 incorporated lifestyle changes or are using over-
2 the-counter products.

3 DR. EGGERS: Okay. Thank you. So we
4 have a lot to cover. Again what we are looking
5 for is really how these overall are changing in
6 how you feel symptoms. And in how they are
7 addressing your overall need for therapies of any
8 kind.

9 MS. WHITTAKER: Excuse me, Sara, can we
10 ask for clarification on the Web as to how many
11 patients are taking prescription?

12 DR. EGGERS: Yeah, how many are taking
13 prescription?

14 MS. GIAMBONE: We had 18 percent taking
15 prescription medication.

16 DR. EGGERS: Okay. So we will begin
17 with medical treatments, medical therapies. And
18 we are actually going to start with
19 investigational drugs. Barbara mentioned and
20 investigational drug, Flibanserin. And we are
21 wondering -- first of all how many of you here
22 have taken an investigational drug, Flibanserin or

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1 anything else that would like to share your
2 experience with that?

3 Okay. Here.

4 So what we are really interested in
5 again is what noticeable changes are you feeling
6 and what and how do you know that those -- how you
7 know that those changed, what you perceived
8 differently and how meaningful those are to you.

9 AMANDA: I was on the Flibanserin trial
10 but -- I'm Amanda. I'm sorry. As you know the
11 trial was stopped. I also had tried Testosterone
12 before that off-label. Unfortunately I found that
13 worked better in the gym for me than it did in the
14 bedroom. But when I was on Flibanserin it did not
15 take long, much like Barbara's experience. It
16 took a few weeks before I noticed a dramatic
17 difference. Going from no thoughts during the day
18 and really no desire, no initiation to suddenly
19 texting and earlier when we were talking about
20 visual clues and written things I always say it
21 was like I'd text him in the middle of the day and
22 get a flutter and I did not mean in my heart, in

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1 the middle of the day for no apparent reason and
2 frequently we would opt to skip dessert at dinner
3 and go home. So I noticed an initial change very
4 early on. I would say I began initiating where I
5 had not in a long time. And likewise virtually no
6 side affects whatsoever. So I was also devastated
7 when that trial ended.

8 DR. EGGER: Any other comments? We are
9 going to talk about Testosterone and other hormone
10 products in a little bit. Any other -- one other
11 investigational drug, a trial that you were in to
12 demonstrate how you saw changes in symptoms or did
13 not?

14 Okay. We have one in the back. We'll
15 get a microphone to you.

16 MS. GUESS: Hi, I'm Marsha Guess. I am
17 actually a physician who treats sexual dysfunction
18 in some women. If you could just expand on your
19 response and how long you used the therapy and how
20 long you responded to the therapy and whether or
21 not your symptoms changed while you were taking
22 that therapy?

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1 DR. EGGERS: Thank you very much. As we
2 go through I think those are great follow up
3 questions as we go through any of these therapies
4 to address.

5 So if there are no more comments. Let's
6 move to Testosterone products because we heard two
7 of you on the panel discuss those. And several of
8 you had mentioned it this morning. There are
9 different types of Testosterone products. So I'm
10 going to ask for some help on a show of hands just
11 to see what the different types that we have.

12 Christy can I put you on the -- a show
13 of hands please for --

14 DR. CHANG: A topical Testosterone,
15 cream, gel?

16 So let's start with FDA approved topical
17 products.

18 DR. EGGERS: For men?

19 DR. CHANG: Yeah, for men?

20 DR. EGGERS: That are used off-label?

21 DR. CHANG: What about for a compounded
22 Testosterone product?

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1 DR. EGGERS: If you have used -- if you
2 are using it now or have used it?

3 DR. CHANG: Injections, Testosterone
4 injections?

5 Testosterone pellets?

6 DR. EGGERS: Okay. So we have the wide -
7 - we run the gamut in terms of experience with the
8 Testosterone products. We won't differentiate for
9 the rest of our conversation but we will just take
10 note that there is a wide variation.

11 Would anyone like to follow up? We
12 heard I'm going to say more successful and less
13 successful experience up here. Would anyone like
14 to follow up first with who feels that they are
15 finding success with their Testosterone product
16 and do you want to explain that?

17 MS. ROBSON: I am Michelle King Robson,
18 excuse me, and I have not been paid to be here
19 today.

20 I suffered from a complete hysterectomy
21 at the age of 42 and tanked. So my hormone levels
22 were gone. And it took me a year and nine doctors

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1 to figure out how to get well. And there were two
2 things, one was estrogen, Estradiol and the other
3 was Testosterone cream. With those two things it
4 changed my life. And it actually caused me to
5 start a company called EmpowHER.com which is
6 women's health online because I almost didn't
7 survive it.

8 One of the things, one of the side
9 effects that I had along with suffering from
10 sexual dysfunction was I had no brain function.
11 My short term memory was gone, I had joint pain, I
12 had sleeplessness, all the things that women have
13 talked about today; hot flashes, night sweats, you
14 name it.

15 This is so common on our sight. It is
16 so disturbing to see what women are faced with
17 every single day and we've got to make changes
18 here. And I am so happy that we are doing this
19 today.

20 DR. EGGERS: Anyone else over there.

21 CARMON: Hi, I talked a little bit
22 earlier but I didn't tell you that I've been

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1 married to my husband for 33 years and we have ten
2 children together and yes we do know what causes
3 that.

4 [Laughter.]

5 And I didn't enjoy it for about 30 years of our
6 marriage. And I am so thankful that we went and
7 had blood tests done and found -- I was grateful
8 to find out that my Testosterone was in the
9 basement. And I am using a product called Axiron
10 which is topical and I put it on under my arm.
11 And it has helped me tremendously. I had not been
12 having orgasms for a long, long time. And I not
13 only can have an orgasm now but I can have
14 multiple orgasms during a sexual encounter with my
15 husband which makes him really happy. It makes me
16 happy.

17 So I am very thankful for that. And one
18 thing my husband has said about using these
19 products to help you when you are having problems
20 with -- I was diagnosed with Hypoactive Sexual
21 Disorder. And one thing that is a good way to
22 think about it is that people have hearing aids,

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1 they have eye glasses to help them when they are
2 vision isn't good. And to treat this like it is
3 some oddity; that it is something we shouldn't
4 look at as another tool that we can have is wrong.
5 It is just another tool in our toolbox and we can
6 use therapy when we have problems. And yeah, I was
7 a busy mom and needed to get more sleep. But the
8 problem was actually physical with me. It wasn't a
9 mental problem.

10 So let's give women another tool that
11 they can use to help enhance their ability to have
12 a better sexual life with their husband or their
13 partner.

14 DR. EGGERS: Thank you.

15 Carmon, right?

16 CARMON: Yes.

17 DR. EGGERS: Can I ask a follow up
18 question. When did you first notice changes after
19 taking the Testosterone?

20 CARMON: It was within weeks.

21 DR. EGGERS: Okay.

22 CARMON: And it has been very steady and

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1 it has been a lot better. It is very noticeable.

2 DR. EGGERS: Thank you.

3 Are there any on the other -- oh, go
4 ahead.

5 BEVERLY: Hi, you probably know who I
6 am. So --

7 DR. EGGERS: Beverly.

8 BEVERLY: My name is Beverly. I have
9 experience with at least four or five of these
10 medications. So I thought it might be beneficial
11 to tell you I started with Testim, topical
12 medication prescribed for men. Unfortunately I
13 had to use so much of it that I smelled like a guy
14 and my girlfriends were attracted to me which
15 really wasn't appealing.

16 [Laughter.]

17 That one had to go because it didn't do anything
18 to help my boyfriend be attracted to me; right.
19 So we switched to Axiron under the arm, great
20 medication. Felt the effects, major stomach
21 upset, had to go off of that one.

22 Then I went to Testosterone injections

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1 in my thighs and I learned to self inject.

2 Fascinating process, lots of bruising, lots of
3 bleeding, lots of drama but it worked.

4 Unfortunately I have an idiosyncratic body that
5 metabolizes medication very quickly, so I went
6 from once a week, to twice a week, and I said this
7 isn't working anymore.

8 Finally I said all right fine, the
9 pellet, we'll try that. It is a beautiful thing.
10 It lasts a long time. It is minor in putting it
11 in but that is the one I've stuck with.

12 I just thought it might be beneficial to
13 hear all of those different medications that are
14 approved for men but not for women but that I've
15 tried. And honestly because I process medication
16 so quickly I could feel a difference within a very
17 short period of time, like a week. So hopefully
18 that helps.

19 DR. EGGERS: Thank you very much.

20 Okay. One more to see someone who has
21 an opposite experience where it hasn't worked for
22 them or that the side effects were such that or

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1 the downsides were such that you choose to not
2 take the product anymore? Oh right, there, yep.

3 KELLY: I'm Kelly and I have done
4 compounded Testosterone and then Testim as well
5 and I didn't see any effect whatsoever. And at
6 that point in time and I didn't even see effect in
7 the gym, like that other lady. I was at least
8 hoping to get something out of it. But at that
9 point in time stopped using that one and then I
10 had also been prescribed Wellbutrin at the
11 beginning to see if that would maybe help me at
12 least enjoy life. And it probably made me kinder
13 to my children but it still didn't give me any
14 better desire. My children thought that I was a
15 nicer mommy at that point in time. But no
16 Testosterone treatment has worked for me as far as
17 those were concerned. And like -- they smell and
18 they are sticky and you think does it -- can it
19 really make a difference and for me it didn't. So
20 right now I am not doing anything. It has just
21 kind of stayed the same.

22 DR. EGGERS: Okay. Yeah, go ahead.

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1 DR. KWEDER: A couple of the folks, I
2 just want to ask you a specific question because a
3 couple of folks who have described success with
4 Testosterone commented on having had their
5 Testosterone blood levels checked.

6 KELLY: Yes.

7 DR. KWEDER: Were you diagnosed with low
8 Testosterone?

9 KELLY: Yes, I was.

10 DR. KWEDER: Thanks.

11 DR. EGGERS: I want to make sure that we
12 keep moving on here. So I'm going to move to
13 other hormonal products that aren't Testosterone.
14 We heard some other mentions of those up here; if
15 anyone would like to share your experiences with
16 any of the other hormone products? Okay. In the
17 back there.

18 MEG: Hi, my name is Meg and yes,
19 Veritas paid for me to come here. I had a
20 hysterectomy; did keep my ovaries. And have once
21 the menopause symptoms started coming on I started
22 taking HRT, a patch. And I can tell an amazing

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1 difference in not only sexual responsiveness but
2 in other areas of my life when I take it and you
3 know the doctors are all like you can only take it
4 for a few years. They are very interested in me
5 weaning off of it for whatever the side effects
6 are. And I am very concerned about what am I
7 going to do when they say that those years are up
8 because I mean that affects all areas of my life
9 including my -- at work how well I can perform. I
10 get the brain fog. I start crying, which I never
11 cry at work. I mean because I have 50 employees
12 and you know you can't cry in front of 50
13 employees. So I am very very concerned that what
14 is there, what is on the horizon, not just for
15 sexual responsiveness but for the other areas in
16 our lives because I mean I am a baby boomer. We
17 are all working longer and longer. Women have
18 these issues and there needs to be some kinds of
19 solutions because we are productive way into our
20 years that in the past you would have been
21 retired. So that is definitely something that I'm
22 interested in and needs to be addressed.

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1 DR. EGGERS: Thank you for sharing that
2 prospective, thank you.

3 Let's move on, there was quite a few of
4 you who talked about over-the-counter products.
5 By the way if we are not getting to the products
6 that you take, please submit those to the Docket
7 or if we can - - maybe we will have some time at
8 the end. But I want to make sure we touch upon
9 some of these. Do you have a comment sir?

10 UNIDENTIFIED PERSON: Can you talk about
11 PDE-5 inhibitors.

12 DR. EGGERS: Can we -- PDE-5 inhibitors?

13 Okay. Can we have a show of hands? How
14 many have taken those off-label? Viagra.

15 Okay. Maybe you could clarify the
16 question for me please.

17 DR. CHANG: PDE-5 inhibitors are
18 medications like Viagra, Cialis, similar
19 medications.

20 DR. EGGERS: Okay. Show of hands. So a
21 number of you have.

22 Yeah.

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1 KAREN: One of the physicians I was
2 seeing recommended that I try Viagra. So I got a
3 very tiny prescription and I tired one pill and
4 the only thing that got swollen were my sinuses
5 and that was it.

6 [Laughter.]

7 DR. EGGERS: Well we -- we will take one
8 more.

9 DR. PARISH: Yes, Sharon Parish from
10 ISSWSH. Just backing up I'd encourage you and urge
11 you to separate the comments of naturally and
12 surgically menopausal women about their treatments
13 from those that are pre menopausal because their
14 experience of hormonal treatments may be very
15 different. And it will confuse the understanding
16 of the patient experience if that is not separated
17 more clearly as we go forward.

18 DR. EGGERS: Great. Okay.

19 So maybe as we do go forward if you feel
20 comfortable saying at what side of the change you
21 are on, that would be helpful for us. And then if
22 you are writing in to expand on your experience in

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1 the Docket if you could similarly let us know
2 that.

3 As far as the over-the-counter products
4 we don't want to spend too much time but I think
5 it would be useful to understand what you're
6 including in this. So would anyone like to just
7 briefly mention what they included in b) when they
8 indicated it?

9 LOUANNE: My name is Louanne, I spoke
10 before.

11 Lubricants obviously, so liquid silk is
12 our favorite but I think the use of a lubricant
13 isn't necessarily a thing that is associated with
14 sexual problems. Some people use it just to
15 enhance pleasure as a starting point even when
16 they are 20 and have plenty of their own natural
17 lubrication to go around. Sexual toys and
18 accessories I guess would perhaps fall into that
19 category too.

20 DR. EGGERS: Anyone who did not include
21 lubricant?

22 Okay. Right here.

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1 CHERYL: Hi, my name is Cheryl and I
2 have tried over-the-counter Provestra and Steel
3 Libido. None have worked for me.

4 DR. EGGERS: We will go to Amanda.

5 AMANDA: I'm Amanda and likewise I did
6 actually order something off the Internet one
7 time. I don't even remember the name of it, that
8 is how sad it is but promised increased libido.
9 That did not work. And my comment about
10 lubricants; they are great as far as physically
11 helping the process but they do nothing for
12 helping your desire.

13 DR. EGGERS: Okay. I see some heads
14 nodding to that.

15 Let's talk about I'm going to put
16 lifestyle changes and behavioral therapies or
17 couples sex therapies and support groups kind of
18 together as things that work on relationships and
19 other things. And we did hear Susan explain that
20 and others have today.

21 Does anyone have an experience with that
22 that is different than what we've already heard

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1 that can expand upon this, like to talk about it?

2 If it has worked for you or hasn't
3 worked for you?

4 Yes.

5 JENA: It is not like a support group.

6 Sorry my name is Jena Umbidwa (ph) and I don't
7 have any financial interest or affiliations.

8 What I found useful was reading about my
9 sexuality because I had the view that I have to
10 have penetration and achieve orgasm through
11 penetration. And it was very stressing for me
12 because this was not the case. And then I started
13 reading about my anatomy and about women's
14 pleasure centers and I read Hite report from Shere
15 Hite and she was pointing out that a lot of women
16 participating in her research were not achieving
17 orgasm through vagina orgasm through penetration.
18 And then I started to problematize that real and
19 also I watched Orgasm Inc. which you should
20 definitely watch it is very informative. Then I
21 started thinking about my sexuality and I found
22 how I can achieve pleasure and this was not the

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1 way that I was learned before that we see in the
2 movies or that is taught to us. So I had this
3 increased knowledge which was reliable. It was a
4 great knowledge and as Mary from the former
5 interview stated it was knowledge from Internet or
6 movies or I don't know other stuff. And I think it
7 has changed my conceptualization of sexuality and
8 my experiences a lot.

9 DR. EGGERS: Jena. Thank you.

10 We will have Sandy follow up.

11 DR. KWEDER: There actually is an FDA
12 approved medical device name of which is escaping
13 me at the moment. Yes, I want to know if anybody
14 -- that isn't one of the choices up there and I'd
15 like to know if folks have had experience with
16 that.

17 DR. EGGERS: Sure. Can we have a show
18 of hand if you have currently or have tried using
19 that device? EROS.

20 DR. KWEDER: I believe it is for sexual
21 arousal disorder and orgasmia. I believe that is
22 the indication.

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1 CAROL: EROS is a device and it is a
2 device to encourage arousal in the vulva and the
3 clitoris and it used to be by prescription only.
4 I don't know if it still is. And it used to cost
5 around \$500. And if you look at their Website and
6 you look at the shape of this device it is very
7 much like a vibrator, different kind of vibrator.

8 DR. EGGERS: Any other follow up
9 questions on medical treatments?

10 Oh, okay, we've --

11 MR. SHIELDS: Thank you. My name is
12 Wayne Shields. I represent an association of
13 health professionals, Association of Reproductive
14 Health Professionals. The reason I'm commenting
15 is not for a medical issue. It is reporting back
16 what my folks tell me that they experience on the
17 front line. My folks are basically the ones who
18 work with clients. And what I hear back from them
19 and I hear this a lot is that there isn't adequate
20 response for this issue with their clients and
21 that there is indeed a subgroup of clients who
22 simply need help with desire, the desire side of

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1 the equation. I agree with some of the folks
2 earlier who mentioned that it is complicated and
3 different for every individual and that is true.
4 But there is definitely a reported group of folks
5 who no matter what have trouble with the desire
6 side of the equation. So I'd encourage us to pay
7 attention to that group even if they are not the
8 majority.

9 DR. EGGERS: Okay.

10 NATALIE: Hi, this is Natalie again. I
11 wanted to make a comment about --

12 DR. EGGERS: Can you hold the microphone
13 closer.

14 NATALLIE: -- about physical therapy,
15 massage and acupuncture and so forth. I had a --
16 like I mentioned before a great sex life with my
17 partner. I didn't change anything. I had an IUD
18 put in, took it out six weeks later. One month
19 later he was on a trip, he got back and it was
20 like a switch that went off. Everything was all
21 of a sudden different. And I went to about ten
22 doctors, hospitals, institutions and everyone said

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1 it was in my head. I throughout that year tried -
2 - we went to couples therapy. We went to sex
3 therapy. I had physical therapy which was very
4 invasive. Acupuncture. I even had a guy go in
5 and do hysteroscopy and laparoscopy to see if he
6 could see anything in the camera that was wrong
7 with me. And it was perfectly normal. And I can
8 talk about how it affected me and how depressed I
9 was and how mal- functional and just horrible it
10 was.

11 But I finally find, I was doing
12 research, a book that got published two months
13 earlier and that is how I found my doctor and he
14 took the hormonal tests and found that I had only
15 20 percent of what was normal for my age group of
16 Testosterone. And literally a week or two after I
17 was treated everything changed and I was fine
18 again.

19 So I just wanted to reiterate that
20 everything else I tried didn't work.

21 DR. EGGERS: Thank you very much.

22 Are there any Web comments on treatments

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1 particularly those we haven't had a chance to
2 discuss yet?

3 MS. GIAMBONE: We heard several
4 treatment options that did not work for some of
5 these participants including BioTE pellet therapy,
6 Testim. In terms of lifestyle changes, meditation
7 did not work. And another participant commented
8 that she was prescribed an anti-depressant and
9 that made her unable to reach orgasm.

10 DR. EGGERS: Thank you.

11 We talked earlier in the afternoon about
12 tracking condition as it changes over time. And
13 there was a lot of difficulty in answering that
14 question because it depends if you are on
15 treatment, if the treatment has natural cycles and
16 everything. And so I think it is useful to follow
17 up on that question again. I am going to pose a
18 side experiment if you went to your doctor and he
19 or she said I am going to start you on this new
20 therapy, whatever therapy you are taking and I
21 want you to track your symptoms given the
22 therapies that you are currently taking are there

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1 variability in those symptoms and please when you
2 are answering the question state which therapy you
3 are on or the combination. But are you noticing
4 changes over time in those therapies as you are on
5 treatment. And if so, if you were asked to
6 identify those treatments over time what time
7 period would you need to use: day, weeks, months,
8 in order to kind of capture that variability as it
9 changes. Hopefully that question made some sense.
10 Any brave souls to try to first answer the
11 question as I posed it?

12 Okay. And then we will go --

13 MS. ROBSON: Michelle King Robson. I go
14 every three months for testing so I do blood work.
15 And it does change so I've been on Hormone
16 Replacement Therapy, the Climara Patch
17 specifically and then I take Testosterone twice a
18 day that is compounded, 1/8th of a teaspoon in the
19 morning and afternoon to keep the consistency and
20 flow the same because a lot of women go like this
21 with their treatment therapies.

22 We test every three months so we do it

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1 by symptom and also by blood work. So she wants
2 to know both because sometimes the blood work can
3 be normal but you are still having some of the
4 symptoms. If I gain a little bit of weight it can
5 change. If I lose a little bit of weight it can
6 change. It really isn't a one size fits all
7 program unfortunately. It is more dependent upon
8 each individual woman as to what they need and
9 what they are going to end up taking.

10 So a lot of it -- it has changed over
11 time, over the past 10, 11 years it is constantly
12 changing and being tweaked. And that is how I
13 stay well and healthy.

14 DR. EGGERS: And that longer time period
15 that you are talking about you are talking three
16 month time period that you revisit do you track in
17 between those three months?

18 MS. ROBSON: I am always tracking.

19 DR. EGGERS: Okay.

20 MS. ROBSON: Yeah. You have to, I mean
21 you really do.

22 DR. EGGERS: Anyone else. I'm sorry

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1 hands went up and I -- we'll go to Sue.

2 MS. WHITTAKER: Can we just go a little
3 bit farther. When you said you are always
4 tracking, how often do you track? And what are
5 you tracking?

6 MS. ROBSON: So I have to track on a
7 daily basis because my medication changes up. One
8 day I'll take one patch, the next day I'll take a
9 different dosage. So it has to be tracked on a
10 daily basis because of the differential in it;
11 right, so and the same with the Testosterone Cream
12 too. So everyday there is a tracking system on my
13 phone actually and I always know when I've
14 forgotten to take something because I will
15 definitely have a side effect or a symptom from
16 it. It is almost immediate. You get to know your
17 body so well.

18 DR. EGGERS: And what type of effects
19 are you tracking when you are -- are you writing
20 down certain symptoms?

21 MS. ROBSON: Yes. I'll write down -- so
22 for example I had heart palpitations and without

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1 getting into great detail of it I went into --
2 because having heart palpitations and being 55
3 years old isn't really a good thing since heart
4 disease is the number one killer of women as we
5 know. I wasn't getting enough estrogen. So when
6 I went into the physician, when I went into the
7 cardiologist they wanted me to take less. They
8 wanted me to go off the estrogen. And then when I
9 went to my primary care physician who is taking
10 care of me she said you need a little bit more.
11 And it actually worked the heart palpitations were
12 gone.

13 Same with joint pain. So joint pain
14 traveled in my body. So if I didn't take the
15 right -- if I wasn't taking the right amount I'd
16 get joint pain.

17 Same with sexual function, libido and
18 brain function. Those are all pretty typical.

19 DR. EGGERS: Thank you.

20 We had a comment over here.

21 SUE: So I'm on a different

22 Testosterone. I am on the pellet. Sue. And the

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1 pellet last approximately six months. But it is
2 individual with each person whether you are a man,
3 whether you are a woman. I mean I think we have a
4 lot more similarities with men than people think
5 about. The Testosterone for me takes four to six
6 weeks to kick in and then the last three to four
7 weeks of that six month period it is pretty much
8 gone. So I can tell by my symptomatology I know
9 that if I have symptoms right after the pellet is
10 put in that they are going to go away. On the
11 other end I don't recognize the symptoms until my
12 HSDD has returned for a few weeks. So for me
13 while I don't track it on a piece of paper it is
14 about a three to four week recall at which point I
15 realize oh, I need a new pellet. I would never --
16 on a daily basis I don't think about it but I'll
17 think back and go oh, I've been thinking a lot
18 about sex lately, I guess the pellet has finally
19 kicked in. It really takes a little longer for
20 recall for myself personally.

21 DR. EGGERS: Okay.

22 We have Amanda.

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1 AMANDA: Amanda. When -- I agree with
2 what she was saying. I still think it is not it
3 for me. I was not a daily process. I don't need
4 to think about it every day. I'm busy. I'm a
5 wife. I'm a mother. I work full time. I can't
6 take the time to think is my level low or I'm
7 going to have to go have something replaced. When
8 I was on the Flibanserin trial we had to fill out
9 a daily diary which was almost comical because
10 quite honestly like I said I'm a mother, I work
11 full time, I don't think about sex 24/7; that is
12 not what it is intended to do. But it is the lack
13 of desire doesn't just go away one day and you
14 take a pill and it returns. I personally don't
15 believe this is a condition that is just going to
16 get better and then you quit. I think it is
17 something that we are going to live with; it is a
18 long term process, it is not a daily tracking. It
19 is more of a weeks and months and future and
20 everything. So it is not like physically you can
21 take it one day and it turns on and you don't have
22 to take it the next day. It is either on or off.

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1 DR. EGGERS: Thank you.

2 So I want to ask a question about --
3 we've talked about symptoms and changing over time
4 and there are two concepts. There is the number of
5 times that you might think of something or that
6 something might happen. And then there is the
7 intensity of that or the strength of it or the
8 quality of it, however you think of it. When you
9 are on these treatments and you are talking about
10 how they affect you, are you thinking about both
11 of those or does one come to mind more the number
12 of them or how do you conceptualize that
13 difference when you are thinking about how well
14 treatments work for you between the number of
15 times, maybe a frequency, with which something
16 returns or the intensity with which it returns?

17 So when you are thinking about how well
18 treatments are working for you how do you
19 conceptualize the difference between the number of
20 times so that you think more often about something
21 or you that you experience something with more
22 intensity, maybe arousal with more intensity? Do

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1 you conceptualize that differently?

2 BEVERLY: It is an interesting question.

3 I heard Sue say her pellets last about six months.

4 Sometimes mine last two months, sometimes they

5 last four months. And I feel the effect right

6 away. So my body just metabolizes it differently

7 than hers. But about three weeks in to four weeks

8 into the pellet I think my Testosterone level goes

9 so high that I think about nothing but sex. I

10 wake up every day thinking about sex. I go to bed

11 every night thinking about sex. And like, okay,

12 really I would like a therapy that worked better,

13 that was more even for me because I end up

14 becoming obsessed with this conversation.

15 [Laughter.]

16 Right. So I go from not being interested at all to

17 not being able to think about anything but that.

18 But then about three weeks later I'm not thinking

19 about it at all and I am like what happened to me?

20 So the rise and fall is definitely more profound

21 for me. And no I don't keep a diary. I have a

22 clear, very clear recollection of when it starts

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1 and when it stops. But hopefully that helps.

2 DR. EGGERS: Karen? We will go with
3 Karen here next.

4 KAREN: I observe that there's a lot of
5 variation in this one particular product that is
6 being used. It is my understanding that it is
7 off-label for women; is that correct?

8 DR. EGGERS: You are talking
9 Testosterone?

10 KAREN: Testosterone, whatever. It is
11 off- label for women.

12 DR. KWEDER: Yes.

13 KAREN: I just observe how interesting
14 it is that all these women have such a different
15 experience with this product that is not FDA
16 recommended for women, approved.

17 DR. EGGERS: Your point has been noted.
18 So we only have -- Oh, go ahead Hylton.

19 MR. JOFFE: I had one question. I was
20 interested in hearing perspectives. It sounds
21 like with treatment such as Testosterone you are
22 talking about something that we take every day.

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1 And I was wondering what folks thought about
2 intermittent treatments where you see this as a
3 condition where you take something when you want
4 to feel more desire as opposed to something you
5 take every day? Does that make sense to anybody?
6 I'd be interested in hearing thoughts on that.

7 DR. EGGERS: We'll go there first.

8 LOUANNE: My name is Louanne. It is
9 funny you asked that because I was just having a
10 thought does this comment fit anywhere in this
11 discussion. I've been using Testim on my calves
12 for 12 years. And I just put a little bit on and
13 rub my calves together while I'm brushing my teeth
14 every morning and that is sort of a two for one
15 kind of thing; that is how I remember to do it
16 every day. And then about this time a year ago my
17 husband was diagnosed with tongue cancer and so
18 here was a big change in our life and lots of
19 surgeries and things changed. And so sex was not
20 on our list of activities for a while. So I just
21 backed off on my Testim which was under my control
22 and I just let it ride until he was feeling back

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1 to a bit of a more normal interest in sexual
2 things. So that is what I think you are asking as
3 life fluctuates can you adjust your treatments and
4 I have. Is that what you are asking?

5 MR. JOFFE: And even one step further
6 intimately using medications from one week to the
7 next or one day to the next, using or not using.
8 Interested if that resonates with anyone or makes
9 sense to anybody?

10 LOUANNE: If I know we are going on
11 vacation to Hawaii I'm usually gearing up the week
12 before. Yeah.

13 [Laughter]

14 One year ago. So yeah in anticipation because
15 Testosterone isn't sort of like you put it on this
16 morning and tonight you feel like wow it is a
17 kicking in thing. For many people it is like a
18 two month process if they are particularly low.
19 For people who kind of just want to ride the top
20 of the wave for whom it works I think they can
21 kind of pull back and forth on the throttle a
22 little bit based on what their plans are and what

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1 their life is like. But I think that what someone
2 over here said. It was Karen I think. I think
3 that there are two probable causes to sexual
4 desire problems. Some of them have to do with
5 Testosterone and some of them have to do with
6 something else completely going on the brain that
7 is different. When people don't get Testosterone
8 to work I think it is a whole different diagnosis.

9 And frankly I was really upset when I
10 saw DSM5 put arousal and interest in the same
11 bullet. I was like what are they thinking about.
12 This is crazy because they are two very different
13 processes. So that was my take as a therapist and
14 a patient. Did that answer your question?

15 DR. EGGERS: We will go with Katherine.
16 Katherine do you have an answer for this question?

17 KATHERINE: I think so. What I was
18 going to say was my sexual dysfunction isn't a
19 physical issue. I have no trouble with orgasm. I
20 have no trouble with any of the other signs. I
21 haven't experienced the change, whatever you are
22 talking about. But I don't even think about sex.

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1 So for me it is not like I'd want to just take a
2 pill right before having sex with my husband. I
3 want to feel it all the time. It can't -- it is
4 not just like a physical thing, like I thought
5 Viagra was just for erectile dysfunction where you
6 take it if you know you are going to have sex.
7 Maybe I'm thinking the wrong drug, I don't know.
8 But this is something I want to experience all the
9 time, 24/7. I want that part of my life back
10 because just thinking about sex, not having it but
11 even just thinking about it impacts the rest of me
12 too. It makes me feel like a more sexual person.
13 It makes me feel like a woman. So I would be
14 interested in not just taking something before
15 having intercourse or if I think I'm going to have
16 intercourse but taking something everyday knowing
17 that those effects are going to last me 24/7/365
18 you know.

19 DR. EGGERS: Thank you very much.

20 Okay. I'm going to move on. We will
21 have time for one caller -- oh we have no callers.
22 Okay.

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1 Then we have more time to explore --
2 okay. We have one more thought. Okay. We will go
3 there first.

4 MS. ROBSON: To answer your question
5 because I've had a complete hysterectomy and had
6 my ovaries removed I couldn't do that. I wouldn't
7 be able to decide when I want to take something
8 right because I'd just be going like this. I'd be
9 roller coasting all over the place. So I need the
10 consistency. And I think to Katherine's point is
11 that what happened with me is I had no desire.
12 Zero. It was gone. It was gone for a long time.
13 And then when I finally got well it came back.
14 And when it came back it was like -- it was pretty
15 remarkable because I had already made the decision
16 that I was just going to live my life that way for
17 the rest of my life at 42 years old. And that is
18 what happens so many times. So I am so thankful
19 that there are options. I just wish that they
20 were FDA approved and they were paid for by
21 insurance. And that is one of the things that we
22 face as women.

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1 DR. EGGERS: So we will take two more
2 comments. We will go to Amanda and then we will
3 come to you.

4 Actually we will go to you first?

5 MS. MODJOROS: I wanted to echo what
6 Katherine said. A lot of my patients don't look
7 at this as a I feel like chicken tonight; I don't
8 feel like chicken tonight. The benefit that
9 Katherine wants, that a lot of my patients want,
10 they want to feel the desire all the time. The
11 converse is what they -- the distress that they
12 feel. I have patients who will wake up and say
13 okay it has been five days, it has been ten days,
14 I have to give my husband sex tonight. They have
15 anxiety all day long. They stress about it. They
16 plan it out. They are like oh, my God I've got to
17 do this and there is not going to be orgasm, there
18 is not going to be arousal and I have to get the
19 lubricant. All of this. And it is because it
20 doesn't come naturally. When they were in their
21 teenage years, when they were in their 20s it may
22 have come naturally for them and that loss of

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1 themselves and that constant preoccupation with
2 what's wrong with me causes distress every day.
3 So if they had an option to take a pill to relieve
4 that distress or take a medication rather to
5 relieve that distress that would be huge for them
6 whereas I don't have many patients that would say
7 I just want one day, I'll do something and you
8 know see what happens. Most of them want all the
9 time.

10 DR. EGGERS: Okay. We are going to go
11 there and then we will come to you Amanda.

12 JENNY: I'm Jenny and I thank Veritas
13 but I would have come anyway. I had accepted the
14 invitation.

15 And I just don't see why we can't have
16 both, the long term and the instant. You have
17 Viagra and Cialis. So I think women should have
18 the option as well of having it both ways.

19 DR. EGGERS: Thank you. And then right
20 here. And then we have time for one more comment
21 with Susan and then we are going to have to wrap
22 up.

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1 AMANDA: So I think we are talking about
2 three separate things and I want to address the
3 question about the intermittent use. It is my
4 understanding from experience and from all the
5 commercials that Viagra works on the spot as a
6 blood flow issue. And I think that for most of us
7 that have lack of desire and are distressed by it,
8 it is not a blood flow issue. I mean you can just
9 send blood down there and I'm going to all of a
10 sudden want to have sex. It is not an issue of
11 not being able to have sex. So what I want is to
12 want to want it all the time to her point over her
13 and Katherine's; I want to always desire my
14 husband and I don't want it to be situational.

15 The Testosterone comment I understand
16 that for some women it works but I think she said
17 it perfectly when it is designed for men and so it
18 is going to vary between women to women and that
19 is a very valid reason why on the packet insert
20 there are strong labels about men using
21 Testosterone staying away from their wife or their
22 spouse for several hours because of the transfer

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1 and the side effects that it can cause. I
2 actually had some of the side effects.

3 The goal for me is to still to have
4 desire for Ben all the time and for it to not
5 cause distress and to just get that desire back
6 and the measuring a satisfying event it goes back
7 to what I said earlier, women don't forget a
8 sexually satisfying event. So I don't need to
9 record that in a diary. I am going to remember
10 that for weeks to come.

11 DR. EGGERS: We are going to go with
12 Karen and then we are going to have to wrap up our
13 -- or Susan, I am sorry Susan. And then we are
14 going to have to wrap up the discussion.

15 SUSAN: I just wanted to say that as I
16 am sitting here listening to this I feel
17 distressed. I feel distressed that we are looking
18 for a drug to basically achieve a perfect sex
19 life. You know when I hear 365 days a week I
20 think that is a lofty goal and I was just thinking
21 that we are talking about distress and I just had
22 to say that I feel distressed that we are looking

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1 for perfection when it comes to sex.

2 DR. EGGERS: Thank you very much Susan.

3 With that -- well, okay, we are going to
4 go with two more comments and we are going to go
5 with the woman in the orange who has had her hand
6 up patiently. And then we will come to you.

7 UNIDENTIFIED PERSON: Hi. I think if you
8 are talking about something a woman could take
9 instantaneously then you are really saying she is
10 only responsive sexual person versus having a
11 subjective sexual desire. And I think that -- I
12 am a sex therapist and I feel like I have had a
13 lot of success treating women without medication
14 but I am here today because I believe that it also
15 gives women a choice. I think that yes, they can
16 work up to it, they can have good erotic
17 stimulation, they can have even a good experience
18 but having the choice to have desire coming into
19 that experience is really erotic and wonderful.

20 DR. EGGERS: Thank you.

21 Okay. So briefly your comment?

22 MARTA: My name is Marta and I'm here

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1 representing an organization Red Hot Mamas which
2 is an educational company for menopausal women.
3 And one of the things I'd like to touch on is a
4 lot of the women that write in on the forum talk
5 about it takes years for them to develop to the
6 point where they are actually able to view it as a
7 problem and to actually seek help. And how many
8 doctors they've gone to that have said there are
9 no options for you. I can't help you. And they
10 are worried about their relationships. They are
11 having a hard time with menopause anyway but they
12 have no libido and there is no outlet, nowhere for
13 them to go. And it is not something you can talk
14 about with your neighbor. So it is a very, very
15 big problem and we need a lot of choices just like
16 men have. And that way women can actually move
17 their lives along. And it is a big deal for
18 marriages and relationships. So I just wanted to
19 point that out there are a lot of women talking
20 about it.

21 DR. EGGERS: Thank you. This has been a
22 very rich discussion filled with many topics that

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1 we could spend days covering and you spend so much
2 of your time thinking about.

3 So again I am going to reiterate we want
4 to hear from you. We only had this amount of time
5 today to do so. But the Docket is available. We
6 do look at all the comments that come in. So
7 please expand upon the thoughts or thing that you
8 want to expand upon that you heard today, please
9 do so.

10 This portion of our discussion is now
11 closing. Again we thank you so much for sharing
12 your very personal experiences and the courage it
13 takes to come up here and do so. So another round
14 of applause from everyone.

15 [Applause.]

16 DR. EGGERS: Another reminder for the
17 evaluation forms they are at the registration
18 table or will be floating around. So please fill
19 those out.

20 And now I will turn it over to Pujita
21 who is going to do the open public comment. So
22 thank you very much.

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1 [Applause]

2 MS. VAIDYA: Hello everyone. I'd like to
3 thank you all for coming here today. And we are
4 now moving into the open public comments session.
5 And for those of you who are not aware the purpose
6 of this session is to allow an opportunity for
7 those who have not had a chance to speak on issues
8 that are not related to our two main discussion
9 topics. This is an opportunity for folks who are
10 not patients or patient representatives to
11 comment.

12 Please keep in mind that we will not be
13 responding to your comments but they will be
14 transcribed and be part of the public record.

15 For the sake of transparency we request
16 that you disclose if you are affiliated with an
17 organization that has an interest in drug
18 development, in FSD, or if your travel here today
19 has been funded by an organization, or if you have
20 significant financial interest in any
21 pharmaceutical companies. If you do not have any
22 such interest, you may state that for the record

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1 as well.

2 So we have collected sign up before the
3 meeting. We have 15 people signed up and about 30
4 minutes for this session. So please be respectful
5 to your other colleagues here and other patients
6 and stick to the two minute limit that we have.
7 We have a timer up front. I have it here. And
8 when the light turns from green to red over here
9 that means your time has ended and I will then ask
10 the next speaker to come to the mic.

11 So I'll run through the order of the
12 speakers and I apologize if I mispronounce your
13 name.

14 So first we will have Leonore Tiefer,
15 Alessandra Hirsch, Thea Cacchioni, Sidney Wolfe,
16 Rebecca Holliman, Judy Segal, Ashland Gena,
17 Kimberly, Sally Greenberg, Deborah Arrindell,
18 Susan Scanlon, Beth, sorry. I'll get back to you,
19 sorry, Sue Goldstein, Amanda, and then Michelle
20 Robson.

21 So first could I have Leonore Tiefer to
22 the mic please? So we have two mics set up, one

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1 to the right and one to the left. So if Leonore
2 could come to one of them and then I'll have
3 Alessandra Hirsch at the other one ready for the
4 next one.

5 DR. TIEFER: Hi. So I'm Leonore Tiefer.
6 I am a New York Psychologist and the founder of
7 the New View Campaign which is a campaign to
8 challenge medicalization. I've thrown my remarks
9 out 12 times. I feel like this has been a surreal
10 meeting. It's -- we are talking at cross purposes
11 with each other. And it was very distressing that
12 we sort of start off this meeting by saying we are
13 committed to developing a drug when, in fact, we
14 can't even agree on what it is for. And we have
15 an over representation of people who are taking
16 drugs paid by drug companies to come and talk
17 about them.

18 This is not the way to do science.
19 There is nothing representative about what is
20 going on here. We have a huge literature on
21 psycho-educational, psycho-therapeutic, self
22 learning, spiritual methods to understand

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1 sexuality. And what I hear here today is there
2 are people who believe deeply in normality. And
3 they had it and they've lost it and they want to
4 go back to it. And then there is the rest of us
5 who believe that the whole thing is a process
6 going forward. It is not a medical model. There
7 is no normal that you lost and you are going back
8 to. It is the wrong way to look at it.

9 We need move conversation. We don't need
10 to move into drug trials.

11 [Applause.]

12 MS. VAIDYA: Thank you.

13 Next Alessandria and then could I get
14 Thea to the mic, please. Thank you.

15 You have to turn it on.

16 MS. HIRSCH: Hello. My name is
17 Alessandra Hirsch. I have a master's degree in
18 physiology from Georgetown University Medical
19 Center. And I currently work as the project
20 manager for PharmedOut which is a program that
21 educates health care professionals on
22 pharmaceutical marketing practices and encourages

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1 evidence based prescribing.

2 I speak to you today as a young woman
3 who is concerned about the implications of
4 treating female sexual dysfunction with
5 Flibanserin and other drugs. And I speak only for
6 myself.

7 When I mentioned to a male friend the
8 idea that the FDA is sexist because it has not
9 approved a female sexuality drug whereas it has
10 approved a bevy of similar drugs for men he
11 laughed at me and said if a good female sex drug
12 had been invented and the FDA were truly sexist it
13 would have been pushed faster than aspirin.
14 Perhaps my friend has a point. What could be more
15 keen to the male interest than a drug that
16 encourages women to have more sex?

17 Let's take that implication a little bit
18 further. I imagine myself in bed with my partner.
19 He initiates a sexual encounter which I rebuff.
20 Today because I have a kind and attentive partner
21 my refusal would not equal rejection but merely a
22 reflection on my mood that day. We would go to

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1 sleep.

2 Years from now with a drug that treats
3 FSIAD on the market he might say to me it is okay
4 that you are not in the mood, why don't you just
5 take your pill for that? What if I still refuse?
6 Do I lose the right to say no because there is a
7 pill to fix me?

8 The scenario that I described seems to
9 me like a very possible outcome in addition to the
10 already exhausting list of micro aggressions that
11 affect women daily.

12 Here are some things that have helped me
13 with period of low libido. My boyfriend,
14 switching boyfriends, chocolate, coffee, certain
15 episodes of Grey's Anatomy, pornography, upgrading
16 my vibrator, the phrase a little to the left, the
17 phrase not so hard, the phrase I love you, reading
18 Fifty Shades of Grey, removable shower head,
19 having tips from my girlfriends, having backrubs,
20 back scratches, a good night sleep and absence of
21 judgment from my boyfriend and an absence of
22 judgment from my friends, a defiance of judgment

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1 from society and an acceptance of myself and the
2 libido I came with.

3 MS. VAIDYA: Excuse me, Alessandria,
4 your two minutes is up.

5 MS. HIRSCH: That is okay. Thank you.

6 [Applause.]

7 MS. VAIDYA: Can I please have Sidney
8 Wolfe to the stand to the right please. Thank
9 you.

10 DR. CACCHIONI: Hi. My name is Thea
11 Cacchioni. I have a Ph.D. in the psychology of
12 sexuality from the University of Warwick, U.K. and
13 I'm a professor at the University of Victoria,
14 British Columbia.

15 I would like to personally thank the FDA
16 for at this point not approving a drug that is
17 unsafe or ineffective. I think there have been
18 enough drugs in the history of women's health as
19 we heard from Karen's comments today that have
20 been approved without enough research.

21 A subtext of the discussion today is
22 that many women's sexual difficulties are the side

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1 effects of drugs that have been approved for the
2 treatment of other conditions. And yet we've also
3 heard a lot about the off-label use of drugs which
4 have not been approved for this reason and that
5 concerns me very much as well as the various ways
6 that they are being used out there in the world.

7 I'd like to just express disappointment
8 to that. This is a patient centered hearing and
9 yet it seems as though it has been mainly people
10 who have been sponsored by industry who have been
11 able to afford to attend. I don't think it is
12 truly representative; not to take away from your
13 experiences.

14 So just to conclude I would like to say
15 it seems as though the line between industry and
16 patient perspectives is very thin.

17 [Applause.]

18 MS. VAIDYA: Thank you.

19 Sidney Wolfe and then could I have
20 Rebecca Holliman to the mic on the left please.
21 Thank you.

22 MR. WOLFE: Sid Wolfe, the Health

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1 Researchers Group. Don't have any financial
2 conflicts of interest. Just one quick comment
3 before the other three quick comments.

4 One, no drugs have been approved for man
5 or women for this purpose. The FDA took a strong
6 position at a hearing last month in September that
7 use of Testosterone for a whole variety of things
8 including pre-sexual desire there is no evidence
9 for it. I got involved in these issues about ten
10 years about when I testified along with Dr. Tiefer
11 at a hearing where they were considering the
12 approval of Testosterone patch for women. The
13 physician who reviewed the drug said "the clinical
14 significance of the increase with active treatment
15 yielding on average of only five to six points
16 more than placebo on a score of 100 for sexual
17 desire is unknown".

18 More recently in 2010 another drug
19 Flibanserin which has been mentioned several times
20 was also turned down and one of the reasons it was
21 turned down again was that the placebo response
22 rate was really quite high. And in an interesting

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1 article by someone who has been here and has
2 spoken, Dr. Kingsberg, after this hearing and
3 after the drug was turned down she commented on
4 the placebo effect. They can be explained by
5 other more psychological factors, for example,
6 women enrolled in these trials that desire to
7 improve their sex lives and take an active role in
8 seeking help. Additionally expectancies for
9 enhanced sexual desire would increase a woman's
10 perception of having desire. Two frequent diary
11 entries which she opposed and which some people
12 today -- were the sum and substance of at least
13 one of the reasons why the placebo worked.

14 And finally before the microphone gets
15 turned off it is a very complicated issue.
16 Everyone has agreed that it is and since we are
17 only about 30 miles from Baltimore where H.L.
18 Makin was. The quote with Makin "for every
19 complicated problem there is a simple solution
20 which is usually wrong".

21 Thank you.

22 [Applause.]

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1 MS. VAIDYA: Thank you.

2 Next we have Rebecca. And then could I
3 get Judy Segal to the mic as well for after.
4 Okay. Go ahead Rebecca.

5 MS. HOLLIMAN: Hi my name is Rebecca
6 Holliman. I'm a graduate student at Georgetown
7 University. And I work as volunteer staff for
8 PharmedOut which is a Georgetown project that aims
9 to encourage evidence based prescribing. I have
10 no financial conflicts of interest.

11 I worry about the potential harm to
12 women if we leave this issue solely in the hands
13 of the medical community. Sex is complicated.
14 Biological function cannot be isolated from
15 physiological, psychological and social factors.
16 It would be a disservice to women to take this
17 approach.

18 The doctor's office can be an
19 intimidating place for women to address concerns
20 about their sexuality. Women are left vulnerable
21 to messages designed to push a profit instead of
22 to educate.

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1 Pills have a higher profit margin than
2 education but opting for the quick fix may cause
3 more harm than good.

4 In an article written by Grant Stoddard
5 he described his experience with having sex on
6 Viagra. In it he made the comment penises are
7 often referred to as tools and that is exactly
8 what mine felt like a wood-like dodonic (ph)
9 prosthesis that was being ridden with little
10 emotional or physical input from me. The
11 experience was strangely feminizing. For the
12 first time I was a passive partner during sex
13 without necessarily being turned on or even having
14 my head in the game.

15 Maybe we have already done men a
16 disservice in focusing on medication to fix the
17 machinery of sex at the same time spreading the
18 message that the body is the only part of them
19 that matters. The emphasis on a medical fix is
20 likely to prove more damaging than helpful to
21 women in the long run. Medical technology is too
22 easily manipulated a device. I can imagine the

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1 commercials already. He made you dinner, he
2 bought you roses, don't you want to be able to
3 respond.

4 A pill or device in a market with
5 inadequate infrastructure to educate women about
6 the non-medical components of arousal is
7 dangerously open to abuse. Once again women will
8 become little more than the functions of their
9 bodies.

10 Thank you.

11 [Applause.]

12 MS. VAIDYA: Thank you.

13 And next we have Judy. And then could I
14 get Alska (ph) Ashley to the mic, please.

15 DR. SEGAL: Hi, my name is Judy Segal.

16 As I mentioned before I'm funded by the Social
17 Science Humanities Research Counsel. I'm a
18 professor at the University of British Columbia
19 and my area of research is discourse language and
20 persuasion in health and medicine.

21 And so I do want to make another comment
22 about some of the language I've heard today.

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1 One of the words that has been missing
2 has come up from time to time but it hasn't been
3 at the center of anything in terms of goals of
4 treatment end points is the word pleasure. It
5 seems to me that a lot of what I've heard about is
6 well interest, arousal, orgasm, husbands, guilt,
7 anxiety, wanting to be free of those but I haven't
8 heard a lot about pleasure. And it seems to me
9 that if we don't talk about sexual pleasure in
10 women as an end point of treatment if there is
11 going to be some kind of treatment then that is
12 say sexist, anti-feminist, in a way that I think
13 not approving drugs that haven't been shown to be
14 safe and effective isn't sexist and anti-
15 feminist.

16 Thank you.

17 [Applause.]

18 MS. VAIDYA: Thank you Judy.

19 Next we have Ashland and can I also get
20 Kimberly to the mic.

21 MS. JERVIS: Hi. My name is Coco Jervis.
22 I will be speaking on behalf of Ashland. I'm the

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1 program director at the National Women's Health
2 Network. The Network talks to patients and other
3 concerned about sexual problems and/or women's
4 health voice information service. The Women's
5 Health Information Service is supported by our
6 members. We do not take any financial
7 contributions from drug companies, medical device
8 manufacturers, insurance companies or any other
9 interest that have a financial stake in the
10 women's health decision making.

11 The Women's Health Voice was launched in
12 1978 and has operated continuously since then.
13 Women routinely contact us with questions about
14 sexual problems. And the questions that they ask
15 us are is this normal? Are my sexual problems
16 caused by something a medical professional did?
17 Does the medical profession have anything to offer
18 me? Does what is being offered work? And what
19 are the risks and side effects of what is being
20 offered? And are there alternatives?

21 What we have found when talking to women
22 with concerns about sexual problems is that good

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1 answers do not exist to any of the questions women
2 ask us. And on behalf of hundreds of women who
3 have brought these questions to us via the Women's
4 Health

5 Voice we want the FDA to know the
6 following: women want more information about what
7 is normal but not just what is hetero-normative.
8 They want to know about natural history studies of
9 changes in sexuality including desire, arousal,
10 and a response with age and reproductive events.
11 Women want more information that is currently
12 available about the effectiveness of medical
13 treatments, procedures and medications on the
14 desire and arousal and satisfaction.

15 Then of course some of them want to know
16 what medical treatments are available. They want
17 to know if treatments they've heard about are
18 legitimate and stringently evaluated by the FDA.
19 They want to know if medical treatments actually
20 work and how well. They want information on about
21 what exactly effective means.

22 Women who contact us with questions

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1 about sexual problems want reliable information
2 about the risks of side effects associated with
3 medical treatments.

4 [Applause.]

5 MS. VAIDYA: Thank you.

6 Next we have Kimberly and can I get
7 Sally on the mic as well. Okay.

8 KMBERLY: Hi. My name is Kim and I am
9 just representing myself. I view myself as a
10 potential patient as a pre-menopausal woman who
11 has young children and as a doctoral student. I
12 understand fatigue and I understand how that
13 affects my own desire.

14 But I am most concerned that any
15 medication that is on the market be both safe and
16 effective for its intended use.

17 And I just wanted to mention how greatly
18 I appreciate that the FDA is dedicated to both
19 safety and true efficacy.

20 Thank you.

21 [Applause.]

22 MS. VAIDYA: Thank you.

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1 So next we have Sally. And then could I
2 also get Deborah.

3 MS. GREENBERG: Good afternoon. My name
4 is Sally Greenberg. I'm the Executive Director of
5 the National Consumers League. We are the oldest
6 consumer organization in the U.S. founded in 1899
7 by pioneering women during the progressive era who
8 focused much of their work on health care and work
9 place protections for women and children. And
10 they fought passionately for women's equality and
11 fair treatment.

12 More recently NCL has been a champion
13 for the safe use of medications and work closely
14 with the FDA on better medication adherence
15 through our Script Your Future Campaign.

16 I'm here today because when it comes to
17 sexual dysfunction treatments and I am going to
18 talk really fast it is clear that we have a gross
19 gender imbalance in products approved for men
20 versus women. With 26 new drugs either approved or
21 marketed for different aspects of male sexual
22 dysfunction including erectile dysfunction,

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1 Peyronie's disease, loss of libido due to
2 hypergonadism.

3 There is nothing so far for women in the
4 most common form of sexual dysfunction, HSDD. And
5 we have to ask the question why? Viagra was
6 approved for erectile dysfunction 16 years ago.
7 It was fast- tracked at the FDA and review in one
8 six month cycle despite a long list of adverse
9 reactions including very serious cardiovascular
10 effects especially if it is co-administered with
11 other commonly used drugs.

12 16 years later despite worthy efforts
13 women still do not have an FDA approved safe and
14 effective treatment for HSDD.

15 This is what women end up doing is they
16 go to the Internet and they buy I have 51 examples
17 here of stuff on the Internet that claims to
18 provide increased libido for women. These
19 treatments are proven neither safe nor effective
20 and because the FDA has dragged its feet and
21 failed to act and address this gender imbalance we
22 have women going and getting products that could

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1 hurt them and waste their money.

2 So if we sound angry; if I sound angry,
3 I am and I think -- congratulate the FDA for doing
4 this workshop here today but we need to move
5 beyond this -- I'm cut off so thank you for your
6 time, you get the picture.

7 [Applause.]

8 MS. VAIDYA: Thank you Sally.

9 We have Deborah ready to speak and then
10 can I get Susan right after her.

11 MS. ARRINDELL: Good afternoon. I'm
12 Deborah Arrindell with the American Sexual Health
13 Association. Our organization was established in
14 1914 when women were largely considered vixens,
15 vectors or infections, and maybe vamps.

16 It is wonderful that we've come to the
17 point where we can begin to talk about women
18 having healthy sexual lives. Women have right
19 perhaps to desire, arousal, even pleasure. So we
20 really appreciate that the FDA has today given
21 organizations like mine and people like me an
22 opportunity to hear from patients which I have

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1 things I have only read about. And what I've
2 heard is despair, anxiety, loss of confidence,
3 loss of self-worth, troubled relationships and
4 families in crises. And sexual health, we
5 believe, is a basic human right.

6 What we've heard is that women will try
7 everything including "some things I don't even
8 remember the names of". And indeed I do believe
9 for some women chocolate, strawberries, and
10 certain episodes of Grey's Anatomy can make a
11 difference. But for many other women that is
12 simply not the case.

13 We heard that for some woman a month in
14 the Caribbean would not do the trick. Not being
15 able to have sexual desire will only add to
16 anxiety there.

17 So I believe that sexual health is a
18 basic human right and those are the women for whom
19 we ask the FDA to provide some options. We don't
20 want a magic pill. We want an opportunity for
21 those women and their providers to together figure
22 out what is right for them and what might work.

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1 I believe that deeply buried in the
2 Constitution there must be a basic right to
3 healthy sexuality. I am going to go with the
4 Pursuit of Happiness.

5 Thank you.

6 [Applause.]

7 MS. VAIDYA: Thank you very much.

8 Next we have Susan. And after that we
9 will have Beth.

10 MS. SCANLAN: Hi. Thank you for letting
11 me speak. I am Susan Scanlan. I am Chair
12 Emeritus of the National Council of Women's
13 Organizations, a coalition of 240 progressive
14 women's groups representing 12 million American
15 women. I am also Chair of Even the Score a
16 coalition of patients, providers, advocates and
17 practitioners who have come together to address
18 the gender disparity in treatments for male versus
19 female sexual dysfunction.

20 There are 26 drugs approved for men and
21 zero for women. Up to one in ten women, American
22 women, suffer from FSIAD. That represents as many

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1 as 16 million women with no answer to this
2 devastating condition.

3 How pervasive is the problem? 75
4 percent of women patients here today are not from
5 the Washington, D.C. area. They are from all over
6 the country. And they need and deserve our help.

7 And let me salute the women who came
8 here and husbands who spoke; so courageous.

9 We support medical treatment for FSIAD.
10 We are tired of hearing that female sexual health
11 is complex as if there would be no answer if we
12 didn't study it. Make no mistake men are equally
13 complex and there has been no shortage of
14 medications to address their sexual dysfunction.

15 In 1960 the birth control pill
16 precipitated a societal shift to recognize women's
17 rights as reproductive beings.

18 In 2014 let's shift to recognize women's
19 rights as sexual beings.

20 Thank you very much.

21 [Applause.]

22 MS. VAIDYA: Thank you.

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1 Next we have Beth and then Sue.

2 MS. BATTAGLINO: Hi. I'm Beth
3 Battaglino. I'm CEO of HealthyWomen.org, the
4 leading not for profit consumer women's health
5 organization who represents more than five million
6 women annually that visit our Website. And I want
7 to share with you that the top three topics that
8 trend the most women's sexual health continues to
9 be in the top three. So we know that women are
10 seeking information and want information and feel
11 that they need to go to a lot of Websites to find
12 that information because it is an embarrassing
13 topic for so many.

14 I also want to share that we recently
15 did a survey of over 1,000 women and 81 percent of
16 the women that took the survey said that their
17 sexual relationships or lack of sexual
18 relationships is very distressful in their
19 relationship and more than 53 percent of these
20 women said that they've been living with this for
21 more than a year.

22 So it is time that we do something. And

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1 they have more options.

2 I also want to share that Healthy Women
3 will continue to provide women with credible
4 medically researched and vetted information and
5 that is how we have remained in business for over
6 26 years.

7 And I want to thank the FDA for
8 commencing this panel. I think it is important
9 but more importantly I really want to thank the
10 real women and your real voices how powerful and
11 so nice to have your spouses here. So thank you.

12 [Applause.]

13 MS. VAIDYA: Thank you Beth.

14 Next we have Sue and then Amanda.

15 MS. GOLDSTEIN: I am Sue Goldstein. I
16 am a sexuality educator and a clinical researcher.
17 And I'm here representing the everyday patient
18 rather than the large societies. I've interviewed
19 a great number of patients in my lifetime, first
20 to write a book, and then working with them for
21 clinical research.

22 And women are angry. And I'm here to

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1 thank the FDA for bringing up this topic for us
2 being to talk about it. As a sexuality educator
3 one of the messages I would like to say is as long
4 as we hide behind walls and we whisper about what
5 we do; how can we expect everybody out in the
6 community to be comfortable talking about sexual
7 health.

8 Women are afraid to talk to their
9 physicians about their sexual health problems.
10 And if they do, what they are told go get a glass
11 of wine, go away for the weekend. And they know
12 that is not the solution. Yes, you can say sex is
13 complicated. The fact is sex is multi-factorial.
14 It is multi-factorial for women. It is multi-
15 factorial for men. And what we do is we do our
16 best. And we have been able to come up with
17 solutions for men and I'm hoping after this forum
18 the FDA will work with companies so we have
19 solutions for women.

20 But there area women out there who are
21 angry because there is nothing for them and they
22 are being told you can't have a choice. All we are

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1 asking is we're Americans, we have a choice
2 whether we can choose abortion or not, we don't
3 have to go to the back rooms and get coat hangers
4 into our cervixes to abort. We want a choice that
5 if we want to have a biologic therapy in addition
6 to or instead of physical therapy, sex therapy, we
7 need a choice. All we are asking for is a choice.
8 Nobody is telling anybody else they need to take a
9 medication. We are just asking to make those
10 options available.

11 Thank you.

12 [Applause.]

13 MS. VAIDYA: Thank you Sue.

14 Next we have Amanda and then finally
15 Michelle Robson.

16 AMANDA: Thank you. I have a very
17 healthy marriage and we have a very open line of
18 communication. We are not here looking for
19 perfection and Ben is not here to expect me to
20 meet his demands. Instead we are looking for
21 restoration of my sexual desire.

22 As we age we lose things. When we lose

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1 the ability to sleep many of us take a sleep FDA
2 approved medication. Some choose not to treat.
3 When we lose the ability to handle stress some of
4 choose an anxiety medicine that the FDA has
5 approved. Others choose not to. So when we lose
6 our desire to have sex with our husbands do we not
7 have an FDA approved option to choose from. I
8 recognize and respect that some choose not to do
9 that and that is their choice. But as an educated
10 professional woman who understands the risks and
11 benefits associated with taking prescription
12 medicine I would appreciate having the chance to
13 have an FDA approved option to choose from and to
14 allow me the opportunity to work with my physician
15 in finding a solution to this problem.

16 I've heard it said a lot today that it
17 is complex. It is really not. It is really not
18 any more complicated than anything else that we
19 lose.

20 BEN: And I just want to say that men
21 have many options when it comes to sexual
22 dysfunction. Women deserve to have some options

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1 too.

2 Thank you.

3 [Applause.]

4 MS. VAIDYA: Thank you.

5 And finally we have Michelle Robson.

6 MS. ROBSON: Thank you for the

7 opportunity to speak today before the FDA. I have

8 no affiliation which I've already said and I have

9 no financial gain. My name is Michelle King

10 Robson. And I am the founder of EmpowHER.com. We

11 have over three and one half million women coming

12 to our site every single month. What do we see?

13 The top five is sexual health and relationships

14 every single day because we track this on a daily

15 basis.

16 I to suffered from sexual dysfunction.

17 It is one of the reasons why I started the

18 company. I see how women are silently suffering

19 because that is what women do. We don't have

20 options and choices. We need options and choices

21 today.

22 Without the option and choice that I had

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1 to go to compounding and to have an FDA approved
2 patch I would not be standing in this room. I
3 would not have created this company. I would not
4 be helping millions of women around the world who
5 are dealing with health issues.

6 Women's health is underserved. It is
7 very clear that it is very underserved. And it
8 has got to change. We are no longer viewed as
9 just vehicles. We are bearing children and we are
10 contributing to society and paying taxes as well.

11 When I spoke to you in 2010 my story and
12 the data was there and the data hasn't changed and
13 it is now 2014.

14 Generations of women have suffered in
15 silence for far too long, far too long. And it is
16 time for the FDA to act. Please act.

17 Treatments and open doors for research
18 and find more and better solutions and to no
19 longer say no. We deserve no less. Just say
20 yes.

21 [Applause.]

22 MS. VAIDYA: Thank you.

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1 That brings our session to the end. And
2 I would like to call Dr. Sandra Kweder to the
3 stand for our closing.

4 DR. KWEDER: Well, good afternoon,
5 everyone. And I recognize that we are ten minutes
6 before you opportunity to stand up and stretch.
7 So I'm going to try and summarize what we heard
8 today. And I hope you can bear with me because I
9 am looking at my little laptop screen.

10 But I did try to divide my comments into
11 a couple of areas. One of which is separated
12 first by the two panels and also acknowledging
13 some of the general comments that were made.

14 First I want to thank you for all my
15 colleagues here for being here and spending the
16 day in a room that is sometimes a little dark and
17 seats that are often a little uncomfortable. And
18 in particular for expressing yourselves and a
19 willingness to listen if you didn't express
20 yourself to a discussion about a topic that is
21 sometimes a little uncomfortable. And if you have
22 any doubt about that I ask you to think back to

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1 the first panel that got up when Sara got up and
2 tried to generate some discussion. I could see
3 people shifting in their seats. There was a
4 little silence and people are thinking oh my gosh
5 how are we going to fill this afternoon. But
6 quickly you arose to the occasion and I am really
7 glad that you did.

8 I found it very informative and I think
9 I speak for my colleagues in that manner as well.

10 We are not here to solve all the world's
11 problems. That is way beyond any of our pay
12 grades. But we are here to listen and try and
13 respond professionally and thoughtfully to
14 concerns raised by patients who have conditions or
15 concerns that you think that we need to hear
16 about. And you certainly outdid yourselves today
17 in expressing that.

18 I do want to acknowledge and we heard
19 this throughout the comments peppered during the
20 day and at the end in the open public hearing that
21 -- I want to acknowledge that there is a breadth
22 of perspective on the issues that we discussed

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1 today. I would be gravely disappointed if there
2 were not a breadth of perspective. And any time
3 we at the agency tackle something that is
4 difficult there is a wide breadth of perspective
5 and people feel very passionately along that full
6 spectrum. That is just fine.

7 So I will acknowledge that there remains
8 some who are concerned that we need more attention
9 to the etiologies and I use plural and physiology
10 of female sexual disorder conditions that have
11 been the focus of today's discussion particularly
12 they expressed concern about the need to consider
13 the natural variation in sexual desire from one
14 person to the next or over the course of any
15 individual's lifetime and life experiences.

16 Another concern that was expressed was
17 that we always take care not to allow undue
18 influence from the pharmaceutical industry in any
19 discussions of any particular medical condition.

20 And other speakers expressed concern
21 that not enough attention has been paid to
22 addressing treatments for women who are

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1 experiencing this condition that we discussed
2 today and there is actually probably a spectrum of
3 conditions based on the kinds of things people
4 raised their hands about in describing their own
5 circumstances.

6 But acknowledging all that I'd like to
7 try and summarize what we heard from Panel 1 that
8 was so eloquently expressed by the panel members.
9 What was most striking to me was how similar the
10 experiences described by the four panelists seemed
11 to be to those who subsequently expressed
12 themselves in the discussion portion following
13 that panel. I would just recount that 75 percent
14 of you who voted cited no or reduced excitement or
15 pleasure during sexual activity. 75 percent
16 expressed no or reduced non genital sensation
17 during sexual activity. And a large number of you
18 as well particularly made a point to express that
19 your major issue of concern is a lack of any
20 desire to even contemplate sexual activity in the
21 first place.

22 And I would say that was one of the most

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1 important messages for us today was that this
2 complete lack of interest in sexual activity seems
3 to be a really predominant feature that many of
4 you shared often to the point of working hard in
5 your life to avoid any experience in life or
6 circumstance in your day-to-day existence that
7 might result in pressure to engage in sexual
8 activity.

9 There was an expression by many of
10 having great difficulty in becoming sexually
11 aroused at all with some noting that they can't
12 reach orgasm; although most expressed the
13 difficulty in becoming aroused at all as more
14 important than any orgasmia.

15 Many of you expressed a point in time in
16 your life when you recognized that suddenly
17 something changed. For some people it was the
18 birth of a child, for some people it was surgical
19 intervention. There were a variety of things
20 expressed. But you referred to what was -- had
21 always been for most of your life normal very
22 suddenly became different. Although others of you

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1 expressed that the onset of this was different.
2 And some who spoke expressed the importance of
3 factoring in age, the variation in that according
4 to a particular age or period of physiologic
5 differences in a woman's life.

6 One of the things that I heard was that
7 interest is different from arousal. Interest is
8 different from the physiologic process of arousal
9 itself. And arousal may often be generated by
10 interest or physical stimulation but many women
11 experience difficulty in both of those spheres.
12 There is like a Venn diagram where they overlap
13 but they are different.

14 With regard to signs and symptoms it was
15 interesting when Sara brought up the issue with
16 regard to signs and symptoms this discussion of
17 what constitutes a satisfying sexual experience.
18 And some of you expressed that a satisfying sexual
19 experience is not something that is easy to
20 measure. It means different things to different
21 people. But you all raised your hands to indicate
22 that having satisfying sex is different but it is

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1 highly different depending on the individual.

2 Overall I think there seemed to be a
3 convergence on satisfaction being related to some
4 sense of emotional positivity and sense of self
5 worth. To me this is an important component. I
6 think we are going to hear more about that
7 tomorrow when we talk about the aspect of being
8 able to measure sexual satisfaction in clinical
9 studies of new drugs. It is something that is
10 often prominent in the scoring system used. So
11 understanding what is behind those is really,
12 really important.

13 In terms of the effect of the disorder
14 or variations in the disorder on people's lives
15 and functionings all who spoke and this was quite
16 striking indicated what a profound affect this has
17 had on your lives beginning with stressing the
18 effect on your sense of self worth but in
19 particular your relationships. Not and most
20 prominently your relationship with your spouse or
21 significant other or sexual partner but also how
22 that affect impacted you beyond just that one-on-

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1 one relationship. It affected oftentimes your
2 family lives, your relationships with your family,
3 how you felt about yourself in your ability to do
4 other things in your life.

5 Some described a cycle of anxiety and
6 disappointment associated with coping with the
7 condition. And it was noted and duly noted on our
8 part that having some input as we think about
9 measures to assess this condition getting input
10 from partners of women with this disorder may be
11 important in our understanding its impact on
12 people's lives.

13 So to move on to Panel 2 and trying to
14 grasp current approaches to treatment, current
15 treatments and how well they worked I did note
16 among the four panelists there was one panelist
17 who focused most particularly on the facilitated
18 work on relationships and developing a sense of
19 really understanding intimacy itself as part of
20 addressing this disorder. And interestingly it was
21 about one in four and also about 25 percent of the
22 people in the room who had done some sort of work

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1 like that in seeking to address this disorder. So
2 it seems like the panel was quite representative
3 of the people in the room.

4 The types of things that were mentioned
5 included Estrogen treatments, various forms of
6 Testosterone, a lot of emphasis and discussion on
7 Testosterone. And you really reflected a gamut of
8 experience from topical, injected or pellets. And
9 what was also striking was there was a great
10 variation in people's experiences and success in
11 treatment with Testosterone which does suggest
12 that there may be different underlying etiologies
13 of this condition that may respond differently to
14 different hormonal interventions.

15 Estrogens I think we can say that the
16 responses were similarly varied. Several of you
17 mentioned systemic use, noticing improvement in
18 symptoms including more widespread affects that go
19 beyond just sexual function but to other aspects
20 of functioning in day-to-day life particularly
21 those women who had experienced surgical menopause
22 or menopause again going back to the spectrum of

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1 affects, impacts that different stages in life can
2 have on sexual functioning.

3 Interesting that PDE5 inhibitors, the
4 Viagras, the Sildenafil, Cialis and the other
5 things, some have tried them. Those who mentioned
6 them seemed to be not particularly enamored with
7 their effectiveness.

8 And several of you mentioned trying a
9 variety of over-the-counter products to try and
10 address your concerns.

11 Several in the room have participated in
12 clinical trials for Flibanserin and those who did
13 mentioned that they had participated indicated
14 that they had had positive effects from that drug
15 on sexual desire.

16 The side effects that were mentioned
17 were not surprising, in particular I would say the
18 most prominent one was undesired hair growth with
19 Testosterone was the one that was mentioned most
20 often and a variety of other things but didn't
21 seem to have any patterns.

22 As far as an ideal treatment I thought

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1 that discussion was interesting. Overall a
2 subjective -- what most people seemed to desire
3 most was something that would bring them back to
4 what they saw as having a healthy sexual life and
5 desire to engage in sexual activity. It seems to
6 be the most elusive aspect of successful treatment
7 from what I heard today and probably one that
8 needs the most focus in developing therapies.

9 Favor was expressed by some for
10 treatments that can be managed on an as needed
11 basis. But it was also important to some of you
12 that this isn't something that comes and goes,
13 this sense of self worth that one has from being
14 able to have a sense of being a sexual being isn't
15 something that comes and goes, it is kind of a
16 continuum or a continuous desire to feel what one
17 perceives as normal.

18 So I'm not sure there is one ideal. I
19 don't think I came away with a sense that there is
20 one ideal but that there is probably breadth in
21 perspective on this issue. And I think as we
22 proceed and encourage companies to proceed with

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1 considering therapies in this area and using
2 measure and considering clinical trials for any
3 products that are developed in this field; those
4 are factors that we all collectively in here at
5 FDA and academia where people, and in clinical
6 medicine and in the pharmaceutical industry are
7 going to have to probe these issue a little bit
8 further.

9 So I couldn't capture absolutely
10 everything that you expressed. I would have been
11 up here all afternoon because that is how long it
12 took to express these things. But I do hope that
13 I've touched on some of the major themes.

14 I think -- I hope that most of you are
15 planning on being here tomorrow because the
16 discussion will be expanded from this to taking
17 what was said today to thinking about how to
18 measure these things; how to take them into
19 consideration in clinical studies; how to develop
20 a study end point and measures of this of these
21 factors that are so important to you as patients
22 so that in any clinical trial we can do you

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1 justice and really assess therapies and whether
2 they really do achieve the things that you find
3 most important in meeting your needs.

4 So again thank you for your attention.
5 Thank you for your serious consideration of the
6 plethora of issues that we have before us.

7 And I hope many of you will be joining
8 us tomorrow.

9 Thanks very much.

10 [Applause.]

11 (WHEREUPON, the public meeting
12 concluded.)

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1 CERTIFICATE OF NOTARY PUBLIC

2 I, MICHAEL FARKAS, the officer before whom the
3 foregoing deposition was taken, do hereby certify
4 that the witness whose testimony appears in the
5 foregoing deposition was duly sworn by me; that
6 the testimony of said witness was recorded by me
7 and thereafter reduced to typewriting under my
8 direction; that said deposition is a true record
9 of the testimony given by said witness; that I am
10 neither counsel for, related to, nor employed by
11 any of the parties to the action in which this
12 deposition was taken; and, further, that I am not
13 a relative or employee of any counsel or attorney
14 employed by the parties hereto, nor financially or
15 otherwise interested in the outcome of this
16 action.

17 

18
19 MICHAEL FARKAS
20 Notary Public in and
for the State of Maryland

21 My commission expires: 6/27/2018

22 Notary Registration No.: 256324

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1 CERTIFICATE OF TRANSCRIPTION

2 I, CHERYL LaSELLE, hereby certify that I am not
3 the Court Reporter who reported the following
4 proceeding and that I have typed the transcript of
5 this proceeding using the Court Reporter's notes
6 and recordings. The foregoing/attached transcript
7 is a true, correct, and complete transcription of
8 said proceeding.

9

10

11

12

A handwritten signature in cursive script that reads "Cheryl LaSelle".

13

CHERYL LaSELLE
Transcriptionist

14

15

16

17

18

19

20

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22

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